EXHIBIT DX1

TO DECLARATION OF PETER J. GOSS IN SUPPORT OF DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF DR. MICHAEL A. MONT

Expert Report of Dr. Michael A. Mont
In re Bair Hugger Forced Air Warming Devices Products Liability Litigation

June 1, 2017

Corey L. Gordon, Esquire
Blackwell Burke P.A.
431 So. 7th St. Suite 2500
Minneapolis, Minnesota 55415

Re: **Bair Hugger Forced Air Warming Products Liability Litigation**

Dear Mr. Gordon:

At your request, I have prepared this summary of the expert opinions on the issue of general causation I plan to offer in the Bair Hugger multidistrict litigation in federal court in Minnesota.

References and reliance materials upon which I base my opinion are listed in Exhibit A, attached hereto. In addition, I rely upon my background, training, experience and research. My CV, including a list of publications, is attached hereto as Exhibit B. I am being compensated at the rate of $500 per hour for my preparation of this report and testimony. A list of cases in which I have testified as an expert witness is attached hereto as Exhibit C.

MY BACKGROUND

I am an orthopaedic surgeon, board certified by the American Academy of Orthopaedic Surgeons (AAOS). I received my medical degree from the University of Pennsylvania in 1984. From 1984 to 1989, I did a research fellowship, followed by an internship, and then an orthopaedic residency at the Mt. Sinai Medical Center, Department of Orthopaedics, in New York City. From 1989 to 1990, I completed a one-year fellowship in lower extremity joint reconstruction at the Johns Hopkins University Medical Institutions, Department of Orthopaedics

in Baltimore, Maryland. Following this, I stayed on the full-time orthopaedic faculty at Hopkins from 1990 to 2000 as an Assistant and then as an Associate Professor of Orthopaedic Surgery. In 2000, I co-founded the Rubin Institute for Advanced Orthopedics at Sinai Hospital of Baltimore and became the Director of the Center for Joint Preservation and Replacement. I held this position through June of 2017 and had become an Adjunct Associate Professor of Orthopaedic Surgery at Hopkins. As of July 2017, I assumed my present position as Chairman of Orthopaedic Surgery at the Cleveland Clinic, Cleveland, Ohio.

I routinely take care of lower extremity joint arthroplasty patients. I have performed during my professional career over 500 to 700 joint replacement surgeries per year for a total of over 15,000 since 1990. I have typically seen over 6,000 patients per year with approximately half of them being related to knee arthroplasties (although with duties as Chairman this past year my clinical activity has been reduced).

I have been course director of many local, national, and international meetings that deal with hip and knee replacement surgery. Through these meetings, and my training and experience, I know the standard of care for treating patients with multiple medical and surgical issues, including known complications from surgical procedures such as periprosthetic infections (PJIs). This knowledge is garnered not only from my fellow panelists, but also from general orthopaedists in the audience when we go over case reports of patients who have similar issues to the ones presented in this litigation.

I am a member of the American Association of Hip and Knee Surgeons (AAHKS), the Hip Society, the Knee Society, and the International Hip Society. I am on the editorial board of over ten different journals including being the Associate Editor of the *Journal of Arthroplasty*. I have received numerous grants related to knee and hip arthroplasty (greater than 100).

Concerning the topic of lower extremity joint arthroplasty, I have close to 700 peer-reviewed PubMed publications. Many of these are related to the topic of periprosthetic infections.

OPINIONS

The major source of periprosthetic joint infections (PJIs) is the patient's own skin.

It is well-established that the major source of bacteria causing PJIs is the patient's own body, particularly the skin. This is why so many of the preventative efforts in the operating room are directed in this arena. Bacteria exist everywhere on the human body -- in our skin, our gut, etc.-- it is commonly believed that bacteria outnumber the cells in our body by as much as 10 to 1.

A brief discussion about prevention of PJIs is in order to put the above statement into appropriate context as well as to understand a number of points that will be made later on in this report. The factors that are can cause PJIs involve the host and the environment. Host factors include, but are not limited to, smoking, alcoholism, uncontrolled diabetes, renal failure, rheumatoid arthritis, history of infections, and malnutrition, among others. Some of these are modifiable or optimizable before surgery and some are not. These host factors can have an enormous impact on the patient's own bacterial bioburden, as well as the patient's ability to resist infection from endogenous bacteria (bacteria that come from the patient). These host factors can also diminish the ability of the patient to avoid infection from exogenous sources of bacteria (external to the patient) as well. As discussed herein, exogenous sources of bacteria are responsible for a small minority of PJIs.

Preoperative strategies to reduce the risk of PJIs include skin cleansing (bacterial decolonization), and prophylactic antibiotics. Intra-operative strategies include hair clipping (not shaving), skin preparation, surgeon and staff preparation, gloving and gowning, draping, antibiotics in the cement, blood conservation, and overall surgical techniques, including copious wound irrigation.

The operating room environment has a multitude of sources of potential contamination. This should be minimized, as much as possible, by not prolonging surgeries unnecessarily to minimize further skin or wound contamination, minimizing operating room traffic, and being careful about contamination of necessary equipment, e.g. suction tips, blades, saws, light handles, etc. Post-operatively antibiotics are often given and appropriate wound aftercare is administered. Patients may need prophylactic antibiotics before certain medical, dental and/or surgical procedures.

I have conducted substantial research concerning the prevention of PJIs with skin preparations, most notably chlorhexidine. We have shown that advance skin preparation can reduce the incidence of PJIs by 60-70 % or greater. The following is a partial list of my publications in this important arena for infection prevention:

1. Chlorhexidine reduces infections in knee arthroplasty.Johnson AJ, Kapadia BH, Daley JA, Molina CB, Mont MA. J Knee Surg. 2013 Jun;26(3):213-8.

2. Economic evaluation of chlorhexidine cloths on healthcare costs due to surgical site infections following total knee arthroplasty. Kapadia BH, Johnson AJ, Issa K, Mont MA. J Arthroplasty. 2013 Aug;28(7):1061-5.

3. Pre-admission cutaneous chlorhexidine preparation reduces surgical site infections in total hip arthroplasty. Kapadia BH, Johnson AJ, Daley JA, Issa K, Mont MA. J Arthroplasty. 2013 Mar;28(3):490-3.

4. Does Preadmission Cutaneous Chlorhexidine Preparation Reduce Surgical Site Infections After Total Knee Arthroplasty? Kapadia BH, Zhou PL, Jauregui JJ, Mont MA. Clin Orthop Relat Res. 2016 Jul;474(7):1592-8.

5. Preoperative skin disinfection methodologies for reducing prosthetic joint infections. Banerjee S, Kapadia BH, Mont MA. J Knee Surg. 2014 Aug;27(4):283-8.

6. Does Preadmission Cutaneous Chlorhexidine Preparation Reduce Surgical Site Infections After Total Hip Arthroplasty? Kapadia BH, Jauregui JJ, Murray DP, Mont MA. Clin Orthop Relat Res. 2016 Jul;474(7):1583-8.

7. Preoperative chlorhexidine preparation and the incidence of surgical site infections after hip arthroplasty. Johnson AJ, Daley JA, Zywiel MG, Delanois RE, Mont MA. J Arthroplasty. 2010 Sep;25(6 Suppl):98-102

8. Patient Compliance with Preoperative Disinfection Protocols for Lower Extremity Total Joint Arthroplasty. Kapadia BH, Cherian JJ, Issa K, Jagannathan S, Daley JA, Mont MA. Surg Technol Int. 2015 May;26:351-4.

9. Advance pre-operative chlorhexidine reduces the incidence of surgical site infections in knee arthroplasty. Zywiel MG, Daley JA, Delanois RE, Naziri Q, Johnson AJ, Mont MA. Int Orthop. 2011 Jul;35(7):1001-6.

10. A Randomized, Clinical Trial of Preadmission Chlorhexidine Skin Preparation for Lower Extremity Total Joint Arthroplasty. Kapadia BH, Elmallah RK, Mont MA. J Arthroplasty. 2016 Dec;31(12):2856-2861

11. Effectiveness of various hospital-based solutions against community- acquired methicillin-resistant Staphylococcus aureus. Perona PJ, Johnson AJ, Perona JP, Issa K, Kapadia BH, Bonutti PM, Mont MA. J Long Term Eff Med Implants. 2013;23(1):23-9.

Therefore, one can already begin to appreciate the importance of skin decontamination in the prevention of PJIs. The majority of PJIs occurring within 1 year of surgery are initiated through the introduction of microorganisms at the time of surgery through the skin. In fact, the most common causative bacterial organisms, Staphylococcal species, are common skin flora.

The impact of ventilation in operating rooms in the control of infections has been the subject of a great deal of research. There was a time when it was commonly thought that airborne contamination of the operating surgical wound was a major source of infection. Thus, strategies were developed to make the air of ORs, especially those used for joint arthroplasties, as clean as possible. This led to such therapies as the use of laminar flow, systems that blow high velocity HEPA-filtered air around the OR table, as well as "space suits" to exhaust air from the surgical staff outside the surgical field. Recent studies have shown these strategies may be ineffective and indeed potentially harmful. In the United States, the current standard for ORs calls for maintaining positive pressure with at least a minimum number of air exchanges per hour. In addition, filtered air enters the OR generally from the ceiling in a downward manner and is exhausted out the sides of the OR. The levels of filtration and the specifics of the HVAC standards are established by ASHRAE, the American Society of Heating, Refrigerating and Air

Conditioning Engineers. It is my understanding that details concerning OR ventilation and filtration, as well as ASHRAE Standards, are being addressed by other experts. For purposes of my opinions from the standpoint of an orthopaedic surgeon, it is clear that: a) airborne transmission of bacteria plays a very minor role in the formation of PJIs; b) use of such strategies as laminar flow and "space suits" have not proven to be effective at reducing PJIs and, in fact, appear to increase the risk of PJIs; and c) the standard ventilation system in the ORs in the U.S. is turbulent, not laminar. Experiments, cited by Plaintiffs' experts, are inappropriately being used to imply that use of the Bair Hugger disrupts turbulent air flow systems. However, turbulent air systems are not sensitive to airflow disruption in the manner purportedly demonstrated in these experiments involving laminar flow. Therefore, these experiments are irrelevant to the issue of whether the Bair Hugger can cause or increase the risk of PJIs.

A related issue raised by plaintiffs is the number of bacteria necessary to cause a deep periprosthetic joint infection. It is likely that the number of bacteria necessary to inoculate a joint implant sufficient to cause a PJI is less than for a superficial infection, but certainly far more than 1 as has been argued by Plaintiffs' experts. An important factor is the presence of foreign material (prosthesis) that does not have a blood supply, and the fact that the host may be less able to ward off an infection as well as it can for the skin where there is a blood supply and more host immune mechanisms present. However, despite this, large numbers of bacteria are still needed for an infection. For example, close to 100 colony forming units (CFUs) of *S. aureus* are necessary to establish infection if inoculated at the time of a hip hemiarthroplasty in a rabbit model, compared with 10^4 when no implant is placed. This difference is explained by biofilm formation in the case of the foreign body (Southwood RT, Rice JL, McDonald PJ, Hakendorf PH, Rozenbilds MA. 1985. Infection in experimental hip arthroplasties. J. Bone Joint Surg. Br. 67:229–231). To further answer this question, it is important to understand that

bacteria must reproduce in sufficient numbers to overwhelm the host immune response. The metric to describe this is the Infectious Dose or ID50 for that bacteria, which is the number of bacteria required to cause an infection in 50% of exposed hosts. The number of bacteria needed to cause an infection also depends on the host. Patients with normal immune systems are more difficult to infect than immunocompromised patients. The ID50 for most bacterial organisms that cause SSIs and PJIs can range from 10^3 and 10^6, and often greater (millions of cells).

While animal models and biologic plausibility do suggest that the amount of bacteria necessary to cause a PJI is less than that needed to cause an SSI, there are no studies that suggest that the number is as low as 1 or 2 CFUs. The animal model noted above that showed inoculation with 100 CFUs is the lowest number in any animal study. There is no evidence to suggest the idea that fewer CFUs could cause PJIs in humans, and it is likely higher than that.

Particles are not the same as bacteria. Only a small minority of particles carry bacteria and many bacteria may not be viable (alive) when they actually come in contact with the host. Particles, which can be easily measured in real time (as opposed to bacteria, which require sampling and culturing), are commonly used as a surrogate to get a crude "snapshot" of what might be the bioburden in an OR. If particle counts are low, that is an indicator that viable bacterial counts are also low. If particle counts are high, that may suggest that the bacterial burden could also be high, but that is not necessarily the case. Studies have demonstrated that particles are, in general, a poor-to-mediocre surrogate for bacterial measurements.

Plaintiffs' experts rely on experiments conducted by employees and agents of the maker of a competitive warming device that purport to show that use of the Bair Hugger can increase particle counts. In the absence of any other information, these findings would warrant further investigation to see if the demonstrated increase in particle counts correlates with an increase in bacteria. However, there are now nine published studies that have examined that question and

found no increase in bacteria from Bair Hugger use. In addition, researchers connected to the maker of the competitive warming device tried on at least seven occasions to demonstrate that use of the Bair Hugger increased bacteria. These efforts were also unsuccessful and, importantly, were never published. These same researchers published the results of their experiments showing increases in particle counts - the implication of these particle studies was that the increased particles correlated with increased bacteria, which these researchers already knew was not the case (and failed to disclose). Plaintiffs' experts rely on the assertion that particles are a valid surrogate for bacteria generally (which, as discussed above, is itself an inaccurate proposition) and then make the unsupported assumption that, because a handful of experiments demonstrated that the Bair Hugger could, under certain experimental conditions, increase particle counts, then it must also be increasing bacteria. Plaintiffs' experts make this leap without regard to the weakness in the claim that particles can be a valid surrogate for bacteria in general, and without regard to the 16 consistent studies that demonstrate that the Bair Hugger device, regardless of its impact on particle counts, does not increase the bacterial bioburden. Bacteria cause PJIs, not particles. Plaintiffs' efforts to take the weak and controversial evidence that particles may be used as surrogates for bacteria, combine that with limited experimental evidence that the Bair Hugger may increase particles, and then conclude that the Bair Hugger does in fact increase bacteria, in the face of at least 16 studies to show that it does not, is pure sophistry and does not comport with valid scientific methodology.

The multiple studies that show no increase in bacteria with the Bair Hugger device include 9 published and 7 non-published. The following 7 non-published studies are confirmed by resources connected to Dr. Augustine, the maker of a competitive warming device: 1) an effort by McGovern and Reed to culture bacteria; 2) an effort by Legg to culture bacteria; and 3)

five attempts by Albrecht, working for Augustine, to culture bacteria. None were successful and none were published.

The published studies that have looked for and failed to find an increased bacterial bioburden associated with Bair Hugger include the following:

Hall poster 1991
Zink 1993
Dirkes 1994
Avidan 1997
Tumia 2002
Huang 2003
Moretti 2009
Occhipinti 2013
Oguz 2017

Many things in the operating room impact airflow. It was claimed by Plaintiffs' experts that the Bair Hugger can impact airflow in the operating room. In my opinion, even if this was the case, it would be infinitesimal in comparison to so many other sources of airflow generation in the operating room, which include:

1. Surgeon traffic - he or she is performing the procedure and creating continual air-currents directly at the operative site

2. Surgical assistants - the same can be said for the 1 to 3 assistants helping in any lower extremity arthroplasty procedure

3. Nurse or Surgical techs - handing instruments and other measures to help with the procedure

4. Circulating nurses - handing out instruments, prostheses, etc.

5. Other members of operating room team - anesthesiologists, others that enter room, delivering of blood, etc.

6. Doors opening and shutting creating wind currents

7. Moving of lights and other equipment directly creates waves or currents by individual (surgeon or team), as well as the specific object moving

8. Many pieces of equipment in the OR generate air currents, including those that have cooling fans.

The airflow generated by the Bair Hugger, as it emerges from the multiple perforations in the warming blanket, is very gentle. Moreover, the Bair Hugger is placed such that the air blows directly on the patient, underneath multiple drapes, and any airflow that emerges from under the drapes is so low in velocity that it has no impact on the air currents in an OR. This is especially true when one considers all of the other sources of air movement during surgery.

In summary, any current created by the Bair Hugger would be negligible compared to these other sources, and therefore, should be considered non-existent.

There are many sources of heat generation in the operating room that are far in excess of any heat generated from the Bair Hugger device. For example, 4 people involved in the operating room, as well as being much closer to the operative site than a Forced Air Warmer, generate much more heat than the Forced Air Warmer, and there are many more heat sources closer to the field. Heat from the Forced Air Warmer is further away from the field and would be dissipated by approximately the inverse square ($1/r^2$) of the distance, so once again, it would have negligible to no effect.

The many sources of heat in the operating room of lower extremity joint arthroplasties include:

1. Saw blades on bone - with the bone generating heat
2. Batteries that power the saw blades as they are used
3. Many surgeons use hooded gowns with battery packs (space suits), and air is blown inside these suits
4. General overhead lights in any operating room
5. Focused overhead lights directly at field (usually 2 of them)
6. Ancillary hooded lights that many surgeons wear (and the light generating unit)
7. All personnel in operating room, including:
    a. Patient

b. Operating surgeon and direct assistants (often 2 to 4)
c. Anesthesiology team-often 2
d. Circulating nurses, preparation help, assistants (often 2)

8. Machine to process fluid irrigation fluids - vacuum canisters and more substantial canisters used nowadays that generate much heat

9. Often other power sources for special blades used in some surgeries (more often revisions) for burring bone, cement, etc - Anspach/Midas Rex devices generate a tremendous amount of heat

10. Standard electrocautery devices

11. Ancillary cautery devices - Plasmablade, Aquamantis, Canady, and others

12. Various ancillary devices in the operating room by anesthesiologist, e.g. defibrillator, computer, their monitor, etc; their anesthesia machine is a source of heat

Finally, the Forced Air Warmer, which is away from the operative field, and has a negligible effect compared to many of the devices or other sources of heat generation mentioned above. See Exhibit D attached hereto.

HEPA filters do not reduce the bacteria that cause surgical site infections. Plaintiffs argue that the Bair Hugger is defective because it fails to use a HEPA filter and, as a result, the Bair Hugger causes more PJIs than if it had a HEPA filter. This opinion is contradicted by both the microbiology and a recent study demonstrating that a HEPA filter does not reduce PJIs.

A HEPA filter, or high efficiency particle arresting filter, is designed to capture 99.97% of particles the size of .3 microns, which is considered the most penetrating particle size, or MPPS. Particles larger and smaller than .3 microns are captured at a higher rate. Bacteria that cause PJIs are actually much larger than .3 microns. An individual bacterium of the kinds that cause PJIs typically ranges from .7 to 1.2 microns, and these bacteria generally travel in clusters (thus increasing their size) and, if traveling by airborne route, generally travel on fomites that are even larger.

Thus, the HEPA's high capture rate of .3 microns particles is not a relevant consideration for bacteria. The question is what is adequate to capture PJI-causing bacteria? ASHRAE standards call for OR ventilation systems to have filters with a MERV rating of 14 for general surgery. A MERV-14 filter is highly efficient at capturing PJI-causing bacteria. Note: the ASHRAE standards are applicable to the ventilation system, not pieces of equipment used in OR, virtually none of which have filters of any kind.

The Bair Hugger, in fact, has a filter that is rated MERV-14, and if the Bair Hugger were a ventilation system, it would meet ASHRAE standards. The fact that it has its own MERV-14 is, in effect, icing on the cake in that it is filtering air that has already been filtered through the hospital's HVAC system. Because the air from the Bair Hugger is so far removed from the surgical site, as discussed above, it is questionable whether it needs a filter at all. Nevertheless, the MERV-14 filter incorporated in the Bair Hugger is far more than adequate to capture PJI-producing bacteria. A recent study conducted by colleagues of mine at the Cleveland Clinic has, in fact, demonstrated that a HEPA filter does not reduce PJIs when incorporated in a forced air device.

At the Cleveland Clinic, approximately 2 years ago, a switch was made from the Bair Hugger device to the Mistral-Air Forced Air Warming System (Stryker, Portage, Michigan). This forced air warming system included a premium HEPA air filtration system. With a hospital system that performs over 4,000 lower extremity joint arthroplasties per year, this afforded a unique opportunity to compare infection rates with both devices. The abstract for the study has been accepted by the MusculoSkeletal Infection Society (MSIS) and will be presented in August of this year at the MSIS annual meeting. A copy of the abstract to be presented at the MSIS meeting is attached hereto as Exhibit E. Because the MSIS requests that abstracts not be publicly disclosed prior to presentation, I have designated this abstract as confidential. This

designation will no longer be necessary after the MSIS meeting ends on August 5. Of note, the study found that there was no statistically significant difference in infection rates between the Bair Hugger with a MERV-14 filter and the Mistral Air with a HEPA filter. I further note that, with respect to PJIs, the study demonstrated that the infection rate was actually lower with the Bair Hugger than with the Mistral Air, 0.47% vs. 0.77%; however, this difference was not statistically significant (p=0.15).

Based on the foregoing, it is my opinion that a HEPA filter is not necessary for the Bair Hugger, nor would a HEPA filter on the Bair Hugger have any positive impact on PJI rates. It is my further opinion that the Bair Hugger is not defectively designed as a result of it not having a HEPA filter and that the MERV-14 filter it has is more than adequate for the device. The results show no statistical differences in infection rates between the two devices. The clear finding of this study is that the HEPA system does not influence infection rates.

Odds ratio of 3.8 for an infection using the Bair Hugger device in the McGovern, et al. study is fallacious for multiple reasons. The study by McGovern is cited often in the Plaintiffs' expert reports as proof of the Bair Hugger device leading to increased PJIs **(**Forced-air warming and ultra-clean ventilation do not mix: an investigation of theatre ventilation, patient warming and joint replacement infection in orthopaedics. J Bone Joint Surg Br. 2011 Nov;93(11):1537-44. McGovern PD, Albrecht, Belani KG, Nachtsheim C, Partington PF, Carluke I, Reed MR).

The reduction in infection rates shown in the McGovern paper can be explained by the Hawthorne effect, regression to the mean, and most importantly by multiple real confounding factors. The "Hawthorne effect," operated because an educational program was introduced to the entire staff in an effort to reduce infection rates. When individuals are simply being observed, they will perform differently — wash hands more often, take more care in what they

do, and engage in other improved forms of "aseptic technique." These actions will invariably lead to reductions in PJI rates. In addition, the high infection rates during the early part of the study period would also most certainly have experienced a regression to the mean and been reduced. However, what is most important to understand is that there were a multitude of not only hypothetical, but real confounding factors that led to the high reported rates of the Bair Hugger device when compared to the conductive fabric device. During some time periods, infection rates were in fact lower for the Bair Hugger. The following will elaborate on these confounding factors:

a. When one is using a single factor analysis, any conclusions in any report can easily be biased by multiple confounding factors that clearly exist in this report. A multiple regression analysis of variance should have been used for appropriate scientific evidence, and in my opinion, the authors reached erroneous conclusions about the effects of the Bair Hugger device on PJIs. In a true highest level prospective randomized study, one would compare two groups that were matched for as many relevant variables as possible.

b. The conductive fabric device was not the only change made at the time that the Bair Hugger was discontinued, but rather multiple other practices had been implemented, any or all of which could have influenced infection rates: more surveillance (hiring of two dedicated SSI nurses), better infection-control techniques, lowering operating room traffic (as mentioned in #1 above), footwear changes, change to more effective antibacterial wound dressings, no shaving of surgical sites (increases infection rates when performed), screening for methicillin-susceptible staphylococcus aureus (MSSA), prewarming, and switch to chlorhexidine wound preps.

c. A number of infected cases were counted in the Bair Hugger group before the general surveillance methods had been introduced. This obviously favored the conductive fabric group in the analysis.

d. From testimony, infections may have been placed erroneously in the wrong group — erroneously increasing the infection rate for the Bair Hugger group and decreasing the infection rate for the conductive fabric group.

e. There was a notable switch in deep venous thrombosis (DVT) prophylaxis during the time periods studied. Some agents can cause increased bleeding — more hematomas occurred in this study, and this can lead to infections. This would have been a major confounding factor in the study and was particularly interesting to me as the primary author of the American guidelines for DVT prophylaxis, as reflected in the following references:

1. Preventing venous thromboembolic disease in patients undergoing elective hip and knee arthroplasty. Mont MA, Jacobs JJ, Boggio LN, Bozic KJ, Della Valle CJ, Goodman SB, Lewis CG, Yates AJ Jr, Watters WC 3rd, Turkelson CM, Wies JL, Donnelly P, Patel N, Sluka P; AAOS.J Am Acad Orthop Surg. 2011 Dec;19(12):768-76.

2. American Academy of Orthopaedic Surgeons clinical practice guideline on: preventing venous thromboembolic disease in patients undergoing elective hip and knee arthroplasty. Jacobs JJ, Mont MA, Bozic KJ, Della Valle CJ, Goodman SB, Lewis CG, Yates AC Jr, Boggio LN, Watters WC 3rd, Turkelson CM, Wies JL, Sluka P, Hitchcock K. J Bone Joint Surg Am. 2012 Apr 18;94(8):746-

3. Preventing venous thromboembolic disease in patients undergoing elective total hip and knee arthroplasty. Members of 2007 and 2011 AAOS Guideline Development Work Groups on PE/VTED Prophylaxis., Mont M, Jacobs J, Lieberman J, Parvizi J, Lachiewicz P, Johanson N, Watters W. J Bone Joint Surg Am. 2012 Apr 18;94(8):673-4.

In the Jensen study on the same patient population, published approximately one year before the McGovern et al. report, the infection rate was found to be higher in the short-lived rivaroxaban period. Although it did not reach statistical significance (5 of 489 patients vs. 14 of 559 patients, 1% vs. 2.5%, $p = 0.102$), it did prompt a switch. Statistics

are unimportant here. The work is underpowered and no hospital would allow 14 infections (almost three times the rate of the other cohort) to not be addressed. Moreover, it is my understanding that Prof. Holford conducted a re-analysis of the Jensen study using the same inclusion and endpoint criteria used in McGovern and demonstrated that there was a statistically significant impact from rivaroxaban. In fact, it was addressed when noted before switching back to the previously used drug, and therefore is a major confounding factor.

f. Likewise, there was a shift in antibiotic use that certainly could have influenced the infection rates. During a 5 months period of Bair Hugger device use compared to 7 months of conductive fabric use with identical antibiotics and DVT prophylaxis, there were no differences in infection rates.

g. In addition, another unusual aspect of this study is that there was a significantly greater infection rate for hips when compared to knees – these should be roughly equal. This finding calls into question the infection rates at this institution, and suggests the possibility of an aberrant hospital-wide or surgeon-specific issue with surgical technique in hip arthroplasties. If a single surgeon who performs mostly hip procedures is using sub-par technique, this could explain the unusual ratio with hip to knee infections

In summary, when parallel patient populations were compared, they were not statistically different. This is why for the vast majority of the time period, one is not comparing apples to apples, but rather apples to so many different factors, which makes conclusions about the Bair Hugger device from a single observational study completely erroneous. One could have picked any one of the 20 other factors that were changed and reached the same conclusions about that particular factor.

Warming or hypothermia does in fact decrease SSIs and maintenance of normothermia has multiple beneficial effects. Strong evidence of SSI reduction for active warming was found by Kurz (1996) and Melling (2001). Since these two seminal studies, warning has become the standard of care and it would not be possible to obtain IRB approval to conduct a randomized study comparing warming to no warming. Thus, more recent studies have been conducted in other ways and have examined other endpoints as well as infection. The well-established body of medical literature demonstrates that maintaining normothermia in surgical patients results in many benefits including reduced blood loss, reduced need for blood transfusions, reduced cardiac incidents, reduced anesthesia recovery time and time in PACU, reduced pain and need for pain medication, reduced shivering, increased patient comfort, reduced hospital length of stay, and reduced mortality. Moreover, studies continue to demonstrate the importance of maintaining normothermia as part of an infection prevention strategy. As the rates of infection have gone down due to multiple strategies and improved surgical techniques, the ability to demonstrate a significant impact of normothermia on infection rates is more difficult. Nevertheless, it is well accepted that warming reduces infection rates in all surgical categories including orthopaedics. Warming remains the standard of care and is recommended by all medical standards groups.

As one recent paper has noted:

> Maintenance of normothermia in orthopedic surgery has proven to have broad implications from bench top to bedside. Normothermia has been shown to impact everything from nitrogen loss and catabolism after hip fracture to injection rates after elective arthroplasty.

Allen & Jacofsky, Normothermia in Arthroplasty, the Journal of Arthroplasty (2012).

Sterile vs. aseptic concept of the operating room environment: The operating room is not a sterile hood for microbiological experiments. We are simply trying to effectuate a reduction of bacteria which are ever-present. "Dilution is the solution to pollution." We can't

eliminate every bacteria — the only things sterile are the implants and the instruments — but only briefly. One cannot sterilize skin, particularly the lower layers.

When one preps the patient for a total knee or hip arthroplasty, there is a tremendous amount of draping that occurs that isolates the wound from the rest of the operating room. This applies importantly to the anesthesia team, their equipment, and the proximal end of the body, where the Bair Hugger device sits. This prepping for surgery can be extensively illustrated to show how there can be little to no contamination from objects at the front of the operating room table. See Exhibit F, attached hereto.

There are a myriad of potential sources of bacteria in the OR. Besides the patient and the staff, equipment can become contaminated during surgery (e.g., electrocautery tips, drills, other surgical instruments); even with double-gloving, inadvertent nicks of the surgeon's gloves are common, (and often undetected until after surgery); overhead lights, etc. See Exhibit G, attached hereto. The goal of aseptic techniques is not the elimination of every single bacterium, an impossible task; rather, it is the reduction of bacteria to the greatest extent possible without compromising the efficacy of the surgery. Thus, aseptic practices speak in terms of "log reductions" in bacteria counts, not sterilization. This is an important concept to remember when assessing any theoretical impact that a device such as the Bair Hugger could have on the bacterial burden in the operative field.

Variations in skill of surgeon or surgical technique can markedly influence infection rates. Many surgeons will perform 5 per month vs. 50 to 100. Also, there can be tremendous variations by institution. This can have a major impact on PJI rates.

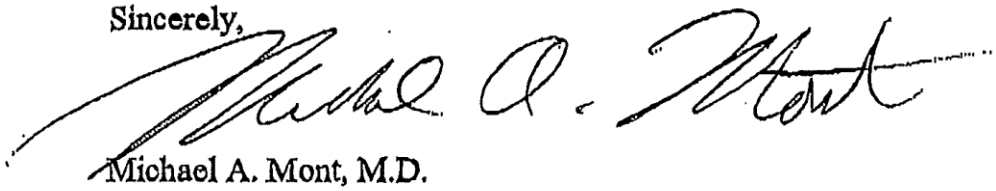
SUMMARY

It is my opinion that the Bair Hugger is not defectively designed. It is safe and effective at maintaining normothermia, which in turn confers a wide range of benefits on the patient,

including reduction of infection risk. Further, use of the Bair Hugger does not cause PJIs nor does it contribute in any way (let alone in a substantial way) to the risk of developing a PJI.

All of the above opinions are held to a reasonable degree of medical certainty. I reserve the right to supplement this report should I receive any additional information relevant to my opinions.

Sincerely,



Michael A. Mont, M.D.

June 2, 2017

EXHIBIT A – REFERENCES AND MATERIALS CONSIDERED

Plaintiffs' Expert Reports

Plaintiffs' Expert Report of Michael W. Buck

Plaintiffs' Expert Report of Yadin David

Plaintiffs' Expert Report of Said Elghobashi

Plaintiffs' Expert Report of William Jarvis

Plaintiffs' Expert Report of Dan Koenigshofer

Plaintiffs' Expert Report of Dr. Jonathan M. Samet

Plaintiffs' Expert Report of Dr. Michael J. Stonnington

Defendants' Expert Reports

Defendants' Expert Report of Theodore R. Holford, Ph.D.

Depositions and Exhibits

Scott Augustine deposition (3.31.17)

Mike Reed deposition (12.4.16)

Paul McGovern depositions (1.4.17 & 1.5.17)

Mark Albrecht depositions (10.7.16 & 11.12.17)

David Leaper deposition (12.8.16)

Andrew Hamer deposition (12.4.16)

Andrew Legg deposition (12.1.16)

Robert Gauthier deposition (10.4.16 & 12.15.16)

Plaintiffs' Studies

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Other Articles and Materials (in addition to those specifically cited in my report)

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(revised July, 2016)

CURRICULUM VITAE
MICHAEL ALBERT MONT

HOME:
2176 Delaware Drive
Cleveland Hts., OH 44106
410-654-8781

E-Mail: 1) montm@ccf.org

OFFICE:
Cleveland Clinic
Orthopaedic Surgery
9500 Euclid Ave.
Cleveland, OH 44195
Desk A-41
(216) 444-2434
(216) 445-6255 (FAX)

EDUCATION:

9/72 - 6/76	**The Bronx High School of Science** Bronx, NY
9/76 - 6/80	**The Johns Hopkins University** Baltimore, MD (B.A. - Natural Sciences)
9/80 - 5/84	**University of Pennsylvania School of Medicine** Philadelphia, PA (M.D.)

POSTDOCTORAL TRAINING:

7/84 - 6/85	Intern in Department of Surgery **The Mount Sinai Medical Center** New York, NY
7/85 - 6/86	Fellow in Orthopaedic Research Department of Orthopaedics **The Mount Sinai Medical Center** New York, NY
7/86 - 6/90	Resident in Department of Orthopaedics **The Mount Sinai Medical Center** New York, NY
7/90 - 6/91	Fellow and Assistant Adult Reconstructive Surgery in Department of Orthopaedic Surgery **The Johns Hopkins University School of Medicine** The Good Samaritan Hospital Baltimore, MD

ACADEMIC APPOINTMENTS:

7/90	Clinical Assistant Department of Orthopaedic Surgery at **The Johns Hopkins University School of Medicine** Baltimore, MD
8/91	Assistant Professor Full-Time Staff Department of Orthopaedic Surgery at **The Johns Hopkins University School of Medicine** Baltimore, MD
10/1995-9/2000	Associate Professor Full-Time Staff Department of Orthopaedic Surgery at **The Johns Hopkins University School of Medicine** Baltimore, MD
9/2010-July 2016	Associate Professor Part-Time Staff Department of Orthopaedic Surgery at **The Johns Hopkins University School of Medicine** Baltimore, MD

HOSPITAL APPOINTMENTS:

7/91 - 2002	**The Johns Hopkins Hospital** Department of Orthopaedic Surgery Baltimore, MD
7/91 – 2000	**The Good Samaritan Hospital** Arthritis Division Baltimore, MD
7/91 - 2002	**Bayview Medical Center (formerly Francis Scott Key Medical Center)** Baltimore, MD
9/00 – 2016	**The Sinai Hospital of Baltimore** Director, Center for Joint Preservation & Replacement Director, Rubin Institute for Advanced Orthopedics

07/16 – present	**Cleveland Clinic** Chairman, Department of Orthopaedic Surgery Cleveland, OH

CERTIFICATION:

National Board Medical Examination Part 1	September 1983
National Board Medical Examination Part 2	September 1985
American Academy of Orthopaedic Surgeons	September 1993
Fellow, American Academy of Orthopedic Surgeons	Class of 1995

LICENSURE:

New York State, July 1985 (not active)	# 168826-1
Maryland State, July 1990	# D0040090
Ohio State, July 2016	# 35.129335

CLINICAL DUTIES:

See approximately 4,000 out-patient visits per year
Perform greater than 800-900 surgical procedures per year
(90% hip surgery, knee surgery and osteonecrosis treatment)

TEACHING AND TRAINEE RECORD: (1990- present)

- Clinically co-direct four to five orthopaedic residents each 10 week period
- Co-Director of Orthopaedic Journal Club (1992 - 1999)
- Direct weekly resident teaching conference (1992 - 2010)

Co-direct full-time involvement with:

- Clinical Fellows in Lower Extremity Reconstructive Surgery:
  1991 - Carlos Lavernia, Audrey Tsao, Michael Drakeford
  1992 - Robert Bachner, Vince Yammamoto
  1993 - Kent Boese, Nicholas Alexander
  1994 - Stephen Tankersley
  1995 - Ajoy Sinha, Henri Pierre-Jacques
  1996 - James Wenz, Ronald Delanois, William Lennen
  1997 - David Padden
  1998 - Michael Banks, Aiman Rifai
  1999 - Steve Khan, Mark Rowley
  2000 - Gracia Etienne, Paul Khanuja, Masato Nagao
  2003 - Craig Thomas, Hari Bezwada
  2004 - Zohair Alam
  2006 - Lorenzo Childress
  2007 - Mario Quesada
  2008 - Frank Armocida, Caesar Saenz

2009 - Siraj Sayeed, Camilo Guzman, Akhil Sastry

Research Fellows in Joint Reconstruction:
1991 - Sanjog Mathur
1992 - Adrian Fairbank
1993 - Jose Romero
1996 - Ivan Pacheco
1997 - Taek-Rim Yoon
1998 - Chang Woo Lee
1999 - Shariar Saedi
2000 - Gracia Etienne, Paul Khanuja, Amar Rajadhyaksha
2002 - Phillip Ragland
2005 - German Marulanda, Thorsten Seyler
2006 - Slif Ulrich
2007 - Mike McGrath
2009 - Michael Zywiel
2010 - Aaron Johnson

Resident Research Preceptorships:
1991 - Fred Serna
1992 - Mark Perry
1993 - David Cohen
1994 - Jennifer Lindsey
1995 - Mark Urquhart
1997 - Dawn Laporte
1998 - Emmanuel Hostin
1999 - Kyle Low
2000 to present – Numerous residents (approximately 3 to 4 per year from multiple orthopaedic residency programs.

Medical Student Research Preceptorships
1990 - Marc Urquhart, Hans Trnka
1991 - Greg Horner, David Solacoff
1992 - Joel Mayerson, Hugh Bassewitz
1993 - Richard Lee, Ivan Tomek, Tarun Mullick
1994 - Dawn Mitzner (Laporte)
1995 - Brian Schafer, Tom Myers, Emanuel Hostin, Andy Chen
1996 - Ramu Poreddy, Vivek Mohan, Mesfin Lemma
1997 - Oren Becher, Sherri Chernitsky, Stephanie Holmes
1998 - Rad Payman, Ben Domb, Keith Baumgartner, Akhil Khanna
1999 - Manesh Bawa, John Hickson, Ngu Bonaventure, Oliver Perez
2000 - Michael Shuler, Jared Foran, Bo Okubadejo
2000 -2001- Amar Rajadhyaksha
2002 to present – Numerous medical students (approximately 5 per year from multiple orthopaedic residency programs.

HONORS:

- New York State Regents Scholarship Finalist (1975)
- National Merit Finalist (1976)

- Westinghouse Science Scholarship, Honors Group (1976)
- Biology Congress. New York Academy of Sciences (1976)
- Johns Hopkins University with General Honors (1980)
- Pennsylvania Medical Society-Student Section (Vice President) (1983)
- Who's Who in America on Various Listings (Professionals, Executives, Doctors) (1993-Present)
- The Johns Hopkins Medical Institutions Department of Orthopaedics Teacher of the Year (1999-2000)

GRANT AND OTHER REVIEW BOARDS:

- National Institute of Health: Multidisciplinary Special Emphasis Panel (1995 - Present)
- American Academy of Orthopaedic Surgeons Committee on Orthopaedic Certification (1995 - Present)
- Medical and Chirurgical Faculty of Maryland (1996 - Present)
- Osteoporosis Research Program (Peer review Panel Member) (1996 - Present)
- National Institute of Health Industry Grant Review Board (2000 - Present)

JOURNAL EDITORIAL BOARDS OR REVIEWER:

Journal of Arthroplasty, Assistant Editor (1992-1993)
Journal of Bone and Joint Surgery (Am) (1994 - Present)
Journal of Arthroplasty, Editorial board (1991 - Present)
Clinical Orthopaedics and Related Research (1994 - Present)
The Journal of Rheumatology (1994 - Present)
Association Research Circulation Osseous (1995 - Present)
Clinical Therapeutics (1996 - Present)
Journal of Bone and Joint Surgery (Am) (1997 - Present)
American J Sports Med (1997 - Present)
Journal of Bone and Joint Surgery (Am) (1999 - Present)
American Editorial Board Orthopaedic Technology Review Editorial Board (2000 - Present)

OTHER SOCIETIES:

United States Tennis Association (1971)
Mensa (1974)
American Malacological Society (1987)
Society of American Baseball Resources (1993)

Conchologists of America (1995)

COMMITTEE ASSIGNMENTS:

- Clinical Practice Committee, Department of Orthopaedics, The Johns Hopkins University (1992 - 1994)
- Infectious Disease Control Committee, Good Samaritan Hospital (1993 - 1994)
- Quality Assurance Committee, Good Samaritan Hospital (1993 - 1994)
- Maryland Joint Parade, Secretary and Treasurer (1994 - 1996)
- Tour Committee, Biomaterials Conference, The Johns Hopkins University (1994)
- Orthopaedic - Rehabilitation Critical Pathway Committee, Good Samaritan Hospital (1995)
- American Academy of Orthopaedic Surgeons Committee on Evaluations (1996)
- Education Committee, Department of Orthopaedics (1996)
- Arthritis Foundation, Maryland Chapter Joint Parade Committee (1997)
- Medical Director, Arthritis Surgery Bone Bank (1997)
- Medical Student Education Committee (1997)
- The Johns Hopkins CPA Strategic Plan Goals and long range objectives committee (1999)
- Clinical Practice Committee, Department of Orthopaedics, Sinai Hospital of Baltimore (2000)
- Resident Education Committee, Department of Orthopaedics, Sinai Hospital of Baltimore (2000)
- Co-Director – Rubin Institute of Advanced Orthopaedics (2000)
- Director – Center for Joint Preservation and Reconstruction, Sinai Hospital of Baltimore (2000)

PROFESSIONAL SOCIETIES:	**(Year Inducted)**
Agnew Surgical Society, Philadelphia	(1983)
American Medical Association	
University of Pennsylvania Representative	(1983)
Pennsylvania Medical Society	
Vice-President	(1983)
Bioelectrical Repair and Growth Society	(1986)
Rockefeller University, Bone and Tooth Society	(1987)
Maryland Orthopaedic Society	(1992)
Orthopaedic Research Society	(1992)
Association Research Circulation Osseous	(1992)
Vice President	(1999)
Newsletter Editor	(1999)

Baltimore City Medical Society	(1992)
Baltimore Bone Club	(1992)
Arthritis Foundation, Maryland Chapter	(1993)
American Academy of Orthopaedic Surgeons	(1994)
New York Academy of Sciences	(1994)
Maryland Joint Parade Secretary/Treasurer	(1994)
American Board of Forensic Examiners	(1995)
Southern Medical Association	(1995)
Society for Tennis and Medicine and Science	(1995)
Academic Orthopaedic Society	(1995)
Medical and Chirurgical Society of Maryland	(1996)
Knee Society	(1997)
Eastern Orthopaedic Association	(1997)
Association Orthopaedic Reconstructive Teaching Associates (AORTA)	(1998)
Hip Society	(1999)
National Osteonecrosis Foundation	(1999)
Center for Osteonecrosis Research and Education	(2000)

GRANT AND OTHER SUPPORT:

1. Porous Coated Anatomic (PCA) Total Hip System - Uncemented Use
   Sponsors: Howmedica, Inc., Rutherford, New Jersey, P.I.: Hungerford, D.S., Mont, M.A.:

2. PCA Knee System Uncemented Use
   Sponsors: Howmedica, Inc., Rutherford, New Jersey, P.I.: Hungerford, D.S., Mont, M.A.:

3. PCA Knee and Hip Cemented Use
   Sponsors: Howmedica, Inc., Rutherford, New Jersey, P.I.: Hungerford, D.S., Mont, M.A.:

4. A Pilot Study of Avascular Necrosis (AVN) of the Femoral Head Using MRI to Assess Bone Regrowth Following Core Decompression.
   Sponsors: Genetics Institute/BioImaging Technologies, Boston, Massachusetts
   Study # (9315(BIT-93002GI)
   P.I.: Mont, M.A., Hungerford, D.S.

5. Clinical Investigation of the Treatment of Loosened Total Hip Replacements with Pulsed Electromagnetic Fields.
   Sponsor: American Medical Electronics, Inc., Richardson, Texas
   P.I.: Hungerford, D.S., Krackow, K.A., Mont, M.A.

6. Open fractures of the tibia,
   Study # (G092M175)
   P.I.: Jinnah, R.H., Bhatia, D., Mont, M.A. (responsible faculty member).

7. Enhancement of chondrocyte phenotype from human bone marrow derived cells.
   Sponsor: Good Samaritan Endowment Fund:

PI: Mont, M.A.
Study # (M40.2069)

8. Evaluation of the Effect of Lipid-Clearing Agents on Patients Receiving High Dose Steroids
   Sponsor: Good Samaritan Hospital, Baltimore, Maryland donated MRI time.
   P.I.: Mont, M.A., Hungerford, D.S., Petri, M.

9. Femoral Head Collapse Model: Prevention with Strut Autografting with or without Bone Morphogenetic Protein,
   Sponsor: Orthopaedic Research and Education Foundation, Chicago, Illinois
   P.I.: Mont, M.A., Co-investigators: Hungerford, D.S., Reddi, H., Jones, L.C., Frondoza, C.F., Young, D., Li, S.

10. Clinical evaluation of the Hemovac(®) Autotransfusion System
    Sponsor: Zimmer, Wausau, Indiana
    PI: Mont, M.A., Hungerford, D.S.

11. The Orthopaedic Department Support for research
    $10,000.00 per year (1993-95) for technician report

12. Virtual Reality Model for Musculoskeletal System
    Sponsor: Submitted to National Institute of Health
    PI: Chao, Edmund Y.S., Co-investigators: Mont, M.A., Huo, M.H., MacWilliams, Bruce A.

13. Medical Student Sponsor
    Sponsor: National Institute of Health
    PI: Mont, M.A.

14. Partnership Total Hip System
    Sponsor: Howmedica, Inc., Rutherford, New Jersey
    PI: Hungerford, D.S., Mont, M.A.

15. Resistance to Activated Protein C (APCR) as a Common Cause of Post-hip or Knee Arthroplasty Thrombophlebitis and Pulmonary Emboli
    Sponsor: Orthopaedic Research and Education Foundation, Chicago, Illinois
    PI: Mont, M.A., Co-investigators: Hungerford, D.S., Glueck, C.A., Jones, L.C.

16. Measurement of Serum Lipoprotein A in SLE Patients With and Without Osteonecrosis
    Sponsor: Donated time from all investigators
    PI: Mont, M.A., Co-investigators: Glueck,C., Hungerford, D.S., Petri, M., Zizic, T., Jones, L.C.

17. Thromboprophylaxis with Different Treatment Regimens of Low Molecular Weight Heparin (Fragmin@) vs. Warfarin in Total Hip Replacement - A Multicenter Double-Blind Randomized Study

Sponsor: Pharmacia, Columbus, Ohio
PI: Mont, M.A., Co-investigator: Hungerford, D.S.

18. Virtual Tactical Engagement Simulation
Sponsor: United States Army Research Division
PI: Chao, Edmund Y.S., Co-investigators: Mont, M.A., Huo, M.H., MacWilliams, B.A.

19. Treatment of Early Stage Avascular Necrosis of the Femoral Head Treated with Core Decompression and Adjunctive Pulsed Electromagnetic Fields
Sponsor: Orthofix Inc., Richardson, Texas
PI: Mont, M.A., Co-investigators: Hungerford, D.S., Jones, L.C.

20. Evaluation of the Degree of Effectiveness of the Hot/Ice System 3 to Decrease Pain and Hospital Stay in Patients Receiving Total Knee Replacement and Total Hip Replacement
Sponsor: Intermedics Orthopedics
PI: Hungerford, D.S., Co-investigator: Mont, M.A.

21. A Single-Blind, Randomized, Parallel Group, Standard Treatment Control, Multicenter Study to Assess the Safety and Efficacy of OCTACOL FI5 in Total Knee Replacement Surgery"
Sponsor: Omrix Biopharmaceuticals
PI: Hungerford, D.S., Co-Investigators: Mont, M.A., Lennox, D.W., Jones, L.C., Anderson, M.

22. Carbonated Apatite Bone Cement in a Femoral Defect Model
Sponsor: Submitted to NIH for STTR
PI: Mont, M.A., Co-Investigators: Poser, R.D., Hungerford, D.S., Jones, L.C., Chao, E.Y.S., Einhorn, T.A., Bauer, T.W.

23. Virtual Biomechanical Model
PI: Chao, E.Y.S., Brown, M., Elias, J., Mont, M.A., Barrance, P., TBN

24. An Open-Label, Randomized, Parallel-Group Study Comparing the Pre-Operative Administration of Procrit the Standard of care in Blood Conservation for Primary Total Knee Reconstruction.
Sponsor: Ortho. BioTech
P.I: Hungerford, Co-Investigators: Mont, M.A., Lennox, D.W., Jones, L.C.

25. Use of Fosamax Alendronate Sodium for Osteolysis around Total Hip Replacements. (Pending)
Sponsor: Merck
P.I.: Hungerford, D.S., Co-Investigators: Mont, M.A., Lennox, D.W., Jones, L.C.

26. A Feasibility and Safety Study of Recombinant Human Bone Morphogenetic Protein - 2/Absorbable Collagen Srone (rhBMP-2/ACS) as an Adjuvant Therapy Core Decompression in Patients with Stage I and II Osteonecrosis of the Femoral Head.
Sponsor: Genetics Institute., Boston, Massachusetts
P.I.: Mont, M.A., Co-Investigators: Hungerford, D.S., Jones, L.C., Lennox, D.W.

27. NAFT Trial: Phase I: Sponsor: Pharmacia/Collaborative Clinical Research Inc.
P.I.: Hungerford, D.S., Mont, M.A., Lennox, D.W.

28. A double blind study of Cosamine for the treatment of knee osteoarthritis.
Sponsor: Nutramax, Baltimore, Maryland
P.I.: Hungerford, D.S., Co-Investigators: Mont, M.A., Zizic, T., Jones, L.C., Holt, P., Mehta, M.

29. NAFT Trial: Phase I.
Sponsor: Pharmacia/Collaborative Clinical Research Inc.
P.I.: Hungerford, D.S., Mont, M.A., Lennox, D.W.

30. Ultram: Pain Relief Study
Sponsor: Gordon S. Black Corporation/Ortho-McNeil Pharmaceuticals
P.I. Hungerford, D.S., Mont, M.A., Lennox, D.W.

31. OP-1 for Osteonecrosis of the Femoral Head In a Dog Defect Model
PI: Mont, M.A., Co-Investigators: Hungerford, D.S., Jones, L.C., Kemmler, J.,

32. Limited Femoral Resurfacing for Osteonecrosis of the Femoral Head
PI: Mont, M.A., Co-Investigators: Hungerford, D.S., Amstutz, H.

33. Use of Osteoset for Osteonecrosis of the Femoral Head
PI: Mont, M.A., Co-Investigator: Hungerford, D.S.

34. Hollow Implants for Total Hip Arthroplasty
PI: Inman, Maria. Co- Investigators- Mont, MA, Taylor,EJ
Support: Seeking National Institutes of Health Small Business Investigation Support Grant

35. Conserve Plus Total Hip Resurfacing Arthroplasty
PI: Mont, M.A., Co-Investigator: Rajadhyaksha,AD
Wright Medical Inc. Memphis, Tennessee

36. Stryker Homedica Osteonics
PI: Mont,MA, Co-Investigator: Hungerford, DS.

37. Accolyte Hip System
PI: Mont,MA
Stryker Homedica Osteonics

38. Fragmin Use for Prevention of Deep Venous Thrombosis
PI: Mont, MA. Co-Investigator: Rajadhyaksha, AD.
Pharmacia, Co.

39. Tantulum Implant for Osteonecrosis of the Femoral Head
PI: Mont, MA. Co-Investigator: Rajadhyaksha, AD.

Implex, Co.

40. Effectiveness of Revision Knee Arthroplasty
PI: Mont, MA.
Orthopaedic Research & Education Foundation

41. TissueLink BPS 5.0 Bipolar Sealer – Hemostatis and Healing in Orthopaedic Applications
PI: Mont, MA. Co-Investigators: Etienne, G., Ragland, PS., Fauser, S.
TissueLink Medical, Inc.

42. A Dose Ranging Trial for the Evaluation of the Safety, Tolerability and Efficacy of Odiparcil in the Prevention of Venous Thromboembolism following Total Knee Replacement Surgery
PI: Mont, MA. Co-Investigators: Delanois, RE., Leadbetter, WB.
GlaxoSmithKline

43. A Multi-Center, Randomized, Double-Blind, Pacebo-Controlled, Parallel Design, 2-Arm Study to Investigate the Effect of Aprotinin on Transfusion Requirements and Blood Loss in Patients Undergoing Elective Primary Total Hip Replacement Surgery
PI: Mont, MA. Co-Investigators: Delanois, RE., Leadbetter, WB.
Bayer Pharmaceuticals

44. A Phase IIa, Multi-Center, Multi-National, Open-Label, Dose Ranging Study of the Efficacy, Safety, and Tolerability of Oral DU-176b Administered Once or Twice Daily in the Treatment of Adult Patients Undergoing Total Hip Arthroplasty
PI: Mont, MA. Co-Investigators: Delanois, RE., Leadbetter, WB.
Daiichi Medical Research, Inc.

45. Osteoarthritis of the Knee Registry for Patients Who Have Been Prescribed the BioniCare Stimulator System (Model BIO-1000) for the FDA Cleared Indication, “for use as an adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee and for overall improvement of the knee as assessed by the Physician’s Global Evaluation (see clinical studies)
PI: Leadbetter, WB. Co-Investigators: Mont, MA., Delanois, RE.
BioniCare Medical Technologies, Inc.

46. 1160.24 RE-MOBILIZE – A Phase III, Randomized, Parallel-Group, Double-Blind, Active Controlled Study to Investigate the Efficacy and Safety of Two Different Dose Regimens (75 mg Day 1 Followed by 150mg Day 2-Completion, and 110mg Day 1 Followed by 220mg Day 2-Completion) of Dabigatran Etexilate Administered Orally (Capsules), Compared to Enoxaparin 30mg Twice a Day Subcutaneous for 12-15 Days in Prevention of Venous Thromboembolism in Patients with Primary Elective Total Knee Replacement Surgery
PI: Mont, MA. Co-Investigator: Delanois, E
Boehringer Ingelheim Pharmaceuticals, Inc.

47. A phase I study to determine the safety and biological activity of cell-mediated gene therapy using Tissue-Gene-C in patients with degenerative joint disease prior to total knee arthroplasty (TGC-03-01). Sponsor: TissueGene, Inc. PI: Mont MA. CI: Delanois RE. Support: Approximately $100,000.00 for September 26, 2006 to present.

48. Multi-center clinical trial of the application of tissue repair cell (TRC) therapy of osteonecrosis of the femoral head. Sponsor: Aastrom Biosciences, Inc. PI: Mont MA. CI: Noga S, Delanois RE, McGrath M. Support: Approximately $100,000.00 for August 23, 2007 to present.

49. Long-term safety follow-up of study subjects who were previously enrolled in a TissueGene clinical trial and were administered TissueGene-C (TGC-B106727). Sponsor: TissueGene. PI: Mont MA. CI: Delanois RE. Support: Approximately $20,000.00/year for April 25, 2008 to present.

50. A multi-center, randomized, double-blind, placebo-controlled, parallel-group study to evaluate efficacy, safety, tolerability, and pharmacokinetics of a single intraoperative localized instillation of 4975 in patients undergoing primary unilateral total hip arthroplasty. Sponsor: Anesiva Pharmaceuticals, Inc. PI: Mont MA. CI: Delanois RE, McGrath M. Support: $20,000.00-50,000.00/year for August 22, 2008 to present.

51. Protocol BioCart II 005-06 efficacy and safety of BioCart II in the treatment of chronic symptomatic cartilage defects of the femoral condyle in comparison with microfracture. Sponsor: ProChon Biotech LTD. PI: Mont MA. CI: Delanois RE, McGrath M. Support: Beginning study – April, 2009.

52. An open-label, multiple-dose, multiple-day, non-randomized, single-arm safety study of repeat-doses of DIC075V (intravenous diclofenac solium) in patients with acute post-operative pain. Sponsor: Javelin Pharmaceuticals, Inc. PI: Mont MA. CI: Delanois RE, Zywiel M. Support: Beginning soon.

53. Conserve plus total resurfacing hip system IDE clinical investigation. Sponsor: Wright Medical Technology Inc. PI: Mont MA. Support: Approximately $40,000.00/year from 2000 to present.

54. Stryker support for various research projects. Support: $60,000/year from 2000 to present.

PUBLICATIONS and MANUSCRIPTS ACCEPTED for PUBLICATION: [Includes greater than 1,000 book chapters, peer-reviewed publications and abstracts]

ORIGINAL PEER-REVIEWED REPORTS:

1. Fellner, M.J., Chen, A.S., Mont, M.A., McCabe, J., Baden, M.: Patterns and Intensity of Autofluorescence and its Relation to Melanin in Human Epidermis and Hair. Int. J. Dermatol., 18(9):722-730, 1979.

2. Fellner, M.J., Moshell, A., Mont, M.A.: Pemphigus Vulgaris and Drug Reactions. Int. J. Dermatol., 20(2):115-118, 1981.

3. Hakim, N., Kaufman, J.J., Mont, M.A., Schmukler, R., Oaley, W.J., Lundahl, T., Meadows, H.E., Soifer, T., Siffert, R.S.: A Digital Image Processing Approach to Diagnosis of Osteoporosis. Proceedings 20th Annual Asilomar Conference on Signals, Systems and Computers, Ed. D.M. Etter, IEEE Computer Society Press, 631-633, 1987.

4. Pilla, A.A., Mont, M.A., Nasser, P.R., Khan, S.A., Figueiredo M., Kaufman, J.J., Siffert, R.S.: Non-Invasive Low Intensity Pulsed Ultrasound Accelerates Bone Healing in the Rabbit. J. Orthop. Trauma, 4(3):246-253, 1990.

5. Mont, M.A., Maar, D.C., Krackow, K.A., Hungerford, D.S.: Hoop-Stress Fractures of the Proximal Femur During Hip Arthroplasty. Management and Results in 19 Cases. J. Bone Joint Surg. Br., 74(2):257-260, 1992.

6. Mont, M.A., Sedlin, E.D., Weiner, L.S., Miller, A.R.: Postoperative Radiographs as Predictors of Clinical Outcome in Unstable Ankle Fractures. J. Orthop. Trauma, 6(3):352-357, 1992.

7. Perry, M.D., Mont, M.A., Einhorn, T.A., Waller, J.D.: The Validity of Measurements Made on Standard Foot Orthoroentgenograms. Foot Ankle, 13(9):502-507, 1992.

8. Maar D.C., Mont, M.A., Krackow, K.A., Hungerford, D.S.: Long-Term (Twelve to Eighteen-Year) Follow-Up of Cemented Total Hip Replacements in Patients Who Were Less Than Fifty Years Old. A Follow-Up Note. J. Bone Joint Surg. Am., 74(2):307-308, 1992.

9. Mont, M.A., Maar, D.C., Krackow, K.A., Jones, L.C., Jacobs, M.A., Hungerford, D.S.: Total Hip Replacement Without Cement for Non-Inflammatory Osteoarthrosis in Patients Who Are Less Than Forty-Five Years Old. J. Bone Joint Surg. Am., 75(5):740-751, 1993.

10. Krackow, K.A., Maar, D.C., Mont, M.A., Carroll, C.: Surgical Decompression for Peroneal Nerve Palsy After Total Knee Arthroplasty. Clin. Orthop., 292:223-228, 1993.

11. Krackow, K.A., Mont, M.A., Maar, D.C.: Limited Femoral Endoprosthesis for Avascular Necrosis of the Femoral Head. Orthop. Rev., 22(4):457-463, 1993.

12. Lavernia, C., Mont, M.A., Hungerford, D.S., Hungerford, D.S.: A Common Problem With Cementless Femoral Components. Clin. Orthop., 290:310-312, 1993.

13. Mont, M.A., Maar, D.C., Urquhart, M.W., Lennox, D., Hungerford, D.S.: Avascular Necrosis of the Humeral Head Treated by Core Decompression. A Retrospective Review. J. Bone Joint Surg. Br., 75(5):785-788, 1993.

14. Mont, M.A., Antonaides, S., Krackow, K.A., Hungerford, D.S.: Total Knee Arthroplasty After Failed High Tibial Osteotomy. A Comparison With a Matched Group. Clin. Orthop., 299:125-130, 1994.

15. Krackow, K.A., Mont, M.A., Maar, D.C.: A New Neck Preserving Total Hip Arthroplasty for the Young Patient. Orthopedics, 17(3):253-259, 1994.

16. Mont, M.A., Alexander, N., Krackow, K.A., Hungerford, D.S.: Total Knee Arthroplasty After Failed High Tibial Osteotomy. Orthop. Clin. North Am., 25(3):515-525, 1994.

17. Mont, M.A., Cohen, D.B., Campbell, K.R., Gravare, K., Mathur, S.K.: Isokinetic Concentric Versus Eccentric Training of Shoulder Rotators with Functional Evaluation of Performance Enhancement in Elite Tennis Players. Am. J. Sports Med., 22(4):513-517, 1994.

18. Mont, M.A., Torres J., Tsao, A.K.: Hypocalcemic-Induced Tetany That Causes Triceps and Bilateral Quadriceps Tendon Ruptures. Orthop. Rev., 23(1):57-60, 1994.

19. Cohen, D.B., Mont, M.A., Campbell, K.R., Vogelstein, B.N., Loewy, J.W.: Upper Extremity Physical Factors Affecting Tennis Serve Velocity. Am. J. Sports Med., 22(6):746-750, 1994.

20. Mont, M.A., Maar, D.C.: Fractures of the Ipsilateral Femur After Hip Arthroplasty. A Statistical Analysis of Outcome Based on 487 Patients. J. Arthroplasty, 9(5):511-519, 1994.

21. Chen, F., Mont, M.A., Bachner, R.S.: Management of Ipsilateral Supracondylar Femur Fractures Following Total Knee Arthroplasty. J. Arthroplasty, 9(5):521-526, 1994.

22. Mont, M.A., Torres, J.A., Tsao, A.K.: Hypocalcemic Induced Tetany Causing Triceps and Bilateral Quadriceps Tendon Ruptures. A Case Report and Review of the Literature with a Description of the Surgical Repair Using a Ligament Locking Loop Stitch. Orthopaedics, 23(1):57-60, 1994.

23. Serna, F., Mont, M.A., Krackow, K.A., Hungerford, D.S.: Total Knee Arthroplasty in Diabetic Patients. Comparison to a Matched Control Group. J. Arthroplasty, 9(4):375-379, 1994.

24. Mont, M.A., Mitzner, D.L., Jones, L.C., Hungerford, D.S.: History of The Contralateral Knee After Primary Knee Arthroplasty for Osteoarthritis. Clin. Orthop., 321:145-150, 1995.

25. Mont, M.A., Fairbank, A.C., Yammamoto, V., Krackow, K.A., Hungerford, D.S.: Radiographic Characterization of Aseptically Loosened Cementless Total Knee Replacement. Clin. Orthop., 321:73-78,1995.

26. Mont, M.A., Hungerford, D.S.: Current Concepts Review: Non-Traumatic Avascular Necrosis of the Femoral Head. J. Bone Joint Surg. Am., 77(3):459-474, 1995.

27. Dellon, A.L., Mont, M.A., Krackow, K.A., Hungerford, D.S.: Partial Denervation for Persistent Neuroma Pain After Total Knee Arthroplasty. Clin. Orthop., 316:145-150, 1995.

28. Mont, M.A., Carbone, J.J., Fairbank, A.C.: Core Decompression Versus Nonoperative Management for Osteonecrosis of the Hip. Clin. Orthop., 324:169-178, 1996. [Review]

29. Mont, M.A., Dellon, A.L., Chen, F., Hungerford, M.W., Krackow, K.A., Hungerford, D.S.: The Operative Treatment of Peroneal Nerve Palsy. J. Bone Joint Surg. Am., 78(6):863-869, 1996.

30. Mont, M.A., Mathur, S.K., Krackow, K.A., Loewy, J.W., Hungerford, D.S.: Cementless Total Knee Arthroplasty in Obese Patients. A Comparison with a Matched Control Group. J. Arthroplasty, 11(2):153-156, 1996.

31. Mont, M.A., Serna, F.K., Krackow, K.A., Hungerford, D.S.: Exploration of Radiographically Normal Total Knee Replacements for Unexplained Pain. Clin. Orthop., 331:216-220, 1996.

32. Mont, M.A., Fairbank, A.C., Krackow, K.A., Hungerford, D.S.: Corrective Osteotomy for Osteonecrosis of the Femoral Head. J. Bone Joint Surg. Am, 78(7):1032-1038, 1996.

33. Dellon, A.L., Mont, M.A., Mullick, T., Hungerford, D.S.: Partial Denervation for Persistent Neuroma Pain Around the Knee. Clin. Orthop., 329:216-222, 1996.

34. Urquhart, M.W., Mont, M.A., Michelson, J.D., Krackow, K.A., Hungerford, D.S.: Osteonecrosis of the Talus: Treatment by Hindfoot Fusion. Foot Ankle Int., 17(5):275-282, 1996.

35. Mont, M.A., Mathur, S.K., Frondoza C.G., Hungerford, D.S.: The Effects of Ciprofloxacin on Human Chondrocytes in Cell Culture. Infection, 24(2):151-155, 1996.

36. Mathur, S.K., Mont,M.A., McCutchen, J.W.: Intraoperative Custom Press-Fit and Standard Press-Fit Femoral Components in Total Hip Arthroplasty. A Comparison of Surgery, Charges and Early Complications. Am. J. Orthop., 25(7):486-491, 1996.

37. Mont, M.A., Schon, L.C., Hungerford, M.W., Hungerford, D.S.: Avascular Necrosis of the Talus Treated by Core Decompression. J. Bone Joint Surg. Br., 78(5):827-830, 1996.

38. Pacheco, I., Mont, M.A., Hungerford, D.S.: Non-Traumatic Osteonecrosis of the Femoral Head: Part I: Demographics, Pathogenesis, Diagnosis, and Staging. Bombay Hospital Journal, 38:546-553, 1996.

39. Mont, M.A., Hungerford, D.S., Pacheco, I.: Diagnosis of Avascular Necrosis of the Femoral Head: Part II: Non-Operative and Operative Treatment. Bombay Hospital Journal, 38:554-563, 1996.

40. Mont, M.A., Fairbank, A.C., Petri, M., Hungerford, D.S.: Core Decompression for Osteonecrosis of the Femoral Head in Systemic Lupus Erythematosus. Clin. Orthop., 334:91-97, 1997.

41. Mont, M.A., Tomek, I.M., Hungerford, D.S.: Core Decompression for Avascular Necrosis of the Distal Femur. Long Term Followup. Clin. Orthop., 334:124-130, 1997.

42. Mont, M.A., Urquhart, M.A., Hungerford, D.S., Krackow, K.A.: Intramedullary Goniometer Can Improve Alignment in Knee Arthroplasty Surgery. J. Arthroplasty, 12(3):332-336, 1997.

43. Pierre-Jacques, H., Glueck, C.J., Mont, M.A., Hungerford, D.S.: Familial Heterozygous Protein-S Deficiency in a Patient Who Had Multifocal Osteonecrosis. A Case Report. J. Bone Joint Surg. Am., 79(7):1079-1084, 1997.

44. Mont, M.A., Hungerford, D.S.: Proximally Coated Ingrowth Prostheses. A Review. Clin. Orthop. 344:139-149, 1997.

45. Mont, M.A., Waldman, B., Banerjee C., Pacheco I.H., Hungerford, D.S.: Multiple Irrigation, Debridement, and Retention of Components in Infected Total Knee Arthroplasty. J. Arthroplasty, 12(4):426-433, 1997.

46. Mont, M.A., Glueck, C.J., Pacheco, I.H., Wang, P., Hungerford, D.S., Petri, M.: Risk Factors for Osteonecrosis in Systemic Lupus Erythematosus. J. Rheumatol., 24(4):654-662, 1997.

47. Waldman, B.J., Mont, M.A., Hungerford, D.S.: Total Knee Arthroplasty Infections Associated with Dental Procedures. Clin. Orthop, 343:164-172, 1997.

48. Mont, M.A., Myers, T.H., Krackow, K.A., Hungerford, D.S.: Total Knee Arthroplasty for Corticosteroid Associated Avascular Necrosis of the Knee. Clin. Orthop., 338:124-130, 1997.

49. Tankersley, W.S., Mont, M.A., Hungerford, D.S.: A Second-Generation Cementless Hip Prosthesis: Improved Results Over the First-Generation Prosthesis. Am. J. Orthop., 26(12): 839-844, 1997.

50. Mont, M.A., Einhorn, T.A., Sponseller, P.D., Hungerford, D.S.: The Trapdoor Procedure Using Autogenous Cortical and Cancellous Bone Grafts for Osteonecrosis of the Femoral Head. J. Bone Joint Surg. Br., 80(1):56-62, 1998.

51. LaPorte, D.M., Mont, M.A., Pierre-Jacques, H., Peyton, R.S., Hungerford, D.S.: Technique for Acetabular Liner Revision in a Nonmodular Metal-Backed Component. J. Arthroplasty, 13(3):348-350, 1998.

52. Nahabedian, M.Y., Mont, M.A., Hungerford, D.S.: Selective Denervation of the Knee: Experience, Case Reports, and Technical Notes. Am. J. Knee Surg., 11(3):175-180, 1998.

53. Delanois, R.E., Mont, M.A., Yoon, T.R., Mizell, M., Hungerford, D.S.: Atraumatic Osteonecrosis of the Talus. J. Bone Joint Surg. Am., 80(4):529-536, 1998.

54. Mont, M.A., Jones, L.C., Einhorn, T.A., Reddi, A.H.: Osteonecrosis of the Femoral Head. Potential Treatment with Growth and Differentiation Factors. Clin. Orthop., 355(Suppl):S 314-335, 1998. [Review]

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54. Mont, M.A., Mayerson, J.A., Krackow, K.A., Hungerford, D.S.: Total Knee Arthroplasty in Patients Receiving Workers' Compensation. J. Bone Joint Surg. Am., 80(9):1285-1290, 1998.

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60. Nahabedian, M.Y., Orlando, J.C., Mont, M.A., Delanois, R.E., Hungerford, D.S.: Salvage Procedures for Complex Soft Tissue Defects of the Knee. Clin. Orthop., 356:119-124, 1998.

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62. Mont, M.A., Yoon, T.R., Krackow, K.A., Hungerford, D.S.: Clinical Experience with a Proximally Porous-Coated Second-Generation Cementless Total Hip Prosthesis: Minimum 5 Year Follow-Up. J. Arthroplasty. 14(8):930-939, 1999.

63. Mont, M.A., Yoon, T.R., Krackow, K.A., Hungerford, D.S.: Patellofemoral Complications in Total Knee Arthroplasty: Clinical and Radiographic Results of 121 Consecutive Cases Using the Duracon System. J. Arthroplasty, 14(8):930-939, 1999.

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2017 Publications

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152. Chen, Andrew, Mont, M.A., Krackow, Ken, Hungerford, David S.: Polyethylene Failure after Porous Coated Anatomic Total Knee Athroplasty.

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SUBMITTED MANUSCRIPTS:

1. Wenz, J.F., Mont, M.A., Delanois, R., Hungerford, D.S.: Salvage of Infected total Hip Arthroplasty. Submitted to J. Bone and Joint Surg. (B).

2. Mont, MA; Lee, CW; Sheldon, M; Lennon, WC; Hungerford, DS: Total knee arthroplasty in patients over 50 years of age. Submitted to Journal of Arthroplasty

3. Mont, MA; Haas, S; Mullick, T; Hungerford, DS: Total knee arthroplasty for patellofemoral arthritis. Submitted to Journal of Bone and Joint Surgery-Am.

4. Mont, MA; Rifai, A; Baumgarten, KM; Sheldon, M; Hungerford, DS: Total knee arthroplasty for osteonecrosis. Submitted to Journal of Bone and Joint Surgery-Am.

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ABSTRACTS SUBMITTED TO AAOS - 2001

1. Chernitsky, S.E., Mont, M.A., Jones., L.C., Laporte, D., Hungerford, D.S., McCarthy, E.: Pathology of core specimens from patients with and without corticosteroid associated femoral head osteonecrosis.

2. Payman, K. Rad., Mont, M.A., LaPorte, Dawn., Jones, Lynne C., Mohan, Vivek., Hungerford, David S.: Demographic, Radiographic and Treatment Characterization of Osteonecrosis of the Proximal Humerus.

3. Mont, M.A., Rajadhyaksha, A.D., Domb, B., Jones, L.C., Hungerford, D.: Comparison of Limited Femoral Resurfacing Arthroplasty Versus Total Hip Arthroplasty for Avascular Necrosis of the Femoral Head.

4. Lennon, William., LaPorte, Dawn., Lee, Chang Woo., Mont, M.A., Hungerford, David S.: Total Knee Arthroplasty in Patients who are 50 Years Old or Younger.

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6. Wenz, J.F., Mont, M.A., Hungerford, David S., Lennox, Dennis W., Shaw, James.: Total Knee Arthroplasties for Patients with Extensor Mechanism Deficiency.

7. Mont, M.A., Rifai A., Baumgarten, K., Hungerford, David S.: Avascular Necrosis of the Femoral Condyle in Patients Greater than Sixty Years of Age: A different Entity Then Spontaneous Osteonecrosis.

8. LaPorte, Dawn., Mont, M.A., Pacheco, Ivan., Hungerford, David S.: Anatomy of the Knee Extensor Mechanism: Correlation to Patellofemoral Arthrosis.

9. Mont, M.A., Hungerford, David S.: Conversion of Fully Ankylosed Hips to Total Hip Arthroplasty.

10. Jones, Lynne C., Mont, M.A., Le, Tung., Petri, Michelle., Glueck, Charles., Hungerford, David S.: Coagulopathies - A Risk Factor in the Development of Osteonecrosis.

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14. Mont, M.A., Foran, J., Banks, M., Mears, S., Hungerford, D.S., Krackow, K.: Effects of Obesity on Total Knee Arthroplasty.

15. Waldman, B.N., Mont, M.A.: A meta-analysis review of oral streptococcal infections post-total knee arthroplasty.

16. Mears, S., Bawa, M., Mont, M.A., Hungerford, D.S., Krackow, A., Jones, L.C.: A Comparison of Post-Operative Complications of Total Knee after Ten Day Mean Versus Two Day Mean Length of Stays. (1987 versus 1997).

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21. Waldman, B., Mont, M.A.: Metanalysis of Infected Total Knee Replacements.

22. Waldman, B., Mont, M.A., Hungerford, D.S.: Salvage of Infected Total Hip Replacements.

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ABSTRACTS SUBMITTED TO KNEE SOCIETY 2001:

1. Yoon, Tek-Rim., Krackow, Ken., Hungerford, David., Mont, M.A.: Eliminating Patellofemoral Complications in Total Knee Arthroplasty.

2. Lennon, William., LaPorte, Dawn., Lee, Chang Woo., Mont, M.A., Hungerford, David S.: Total Knee Arthroplasty in Patients who are 50 Years Old or Younger.

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8. Waldman, B.N., Mont, M.A.: A meta-analysis review of oral streptococcal infections post-total knee arthroplasty.

9. Mears, S., Bawa, M., Mont, M.A., Hungerford, D.S., Krackow, A., Jones, L.C.: A Comparison of Post-Operative Complications of Total Knee after Ten Day Mean Versus Two Day Mean Length of Stays. (1987 versus 1997). Baumgarten, K., Rifai, A., Jones, L.C., Mont, M.A., Hungerford, D.S.: Clinical, Radiographic and Treatment Aspects of 301 Osteonecrotic Knees in Patients Under 45 Years of Age.

10. Rifai, A., Baumgarten, K., Mont, M.A., Hungerford, D.S.: Inability of Core Decompression for Spontaneous Osteonecrosis of the Knee.

11. Rifai, A., Baumgarten, K., Mont, M.A., Hungerford, D.S.: MRI Patterns as Predictive of Prognosis in Osteonecrosis of the Knee

13. Waldman, B., Mont, M.A.: Metanalysis of Infected Total Knee Replacements.

ABSTRACTS SUBMITTED TO AAOS – 2002:

1. Rajadhyaksha A.D., Mont M.A., Etienne G., Perez O., Khanuja P., Hungerford D.S.: Outcomes of Limited Resurfacing for Osteonecrosis of the Femoral Head.

2. Mont, M.A., Hungerford D.S., Shaw J.: Total Knee Arthroplasties for Patients with Extensor Mechanism Deficiency.

3. Mears S.C., Mont, M.A., Nixon J.C., Jones L.C., Hungerford D.S.: Spontaneous Osteonecrosis of the Knee is Not a True Osteonecrotic Condition.

4. Jones L.C., Mont, M.A., Le T., Petri M., Glueck C., Hungerford D.S.: Coagulopathies – A Risk Factor in the Development of Osteonecrosis.

5. Mears S.C., Mont, M.A., Nixon J.C., Baumgarten K.M., McCarthy E., Hungerford D.S.:

Secondary Osteonecrosis in Young and Old Patients.

6. Lennen W., Mont, M.A., LaPorte D.M., Lee C.W., Hungerford D.S.: Total Knee Arthroplasty in Patients Who Are 50 Years Old or Younger.

7. Mont, M.A., Rajadhyaksha A.D., Baumgarten K.M., Hungerford D.S.: Avascular Necrosis of the Femoral Condyle in Patients Greater Than Sixty Years of Age: A Different Entity Than Spontaneous Osteonecrosis.

8. Bawa M., Rajadhyaksha A.D., Mont, M.A., Jones L.C., Hungerford D.S.: Shortened Hospital Stays after Total Hip and Knee Arthroplasties Have Decreased Complication Rates.

9. Tortolani P.J., Perez O., Mont, M.A., McCarthy E., Rajadhyaksha A.D., Hungerford D.S.: Rapidly Progressive Hip Disease: Demographic, Histopathic and Radiographic Aspects.

10. Baumgarten K.M., Mont, M.A., Rajadhyaksha A.D., Bluemke D.A., Jones L.C., Hungerford D.S.: The Prognostic Value of Magnetic Resonance Imaging of Avascular Necrosis of the Knee.

11. Hostin E., Mont, M.A., LaPorte D.M., Rajadhyaksha A.D., Jones L.C., McCarthy E., Hungerford: The Pathology of Osteonecrosis of the Femoral Head: A Quantitative Evaluation of Core Decompression Specimens.

12. Baumgarten K.M., Mont, M.A., Rajadhyaksha A.D., Rifai A., Hungerford D.S.: Atraumatic Secondary Osteonecrosis of the Knee in Patients Fifty-Five Years of Age and Older.

13. Mont, M.A., Waldman B., Rajadhyaksha A.D., Hungerford D.S.: Treatment of Infected Knee Arthroplasty Components with Retention.

14. Baumgarten K.M., Mont, M.A., Rajadhyaksha A.D., Jones L.C., Hungerford D.S.: Demographic, Radiographic and Treatment Characterization of Secondary Osteonecrosis of the Knee.

15. Foran J., Rajadhyaksha A.D., Okubadejo G., Mont, M.A., Jones L.C., Hungerford D.S.: Treating Osteoarthritis of the Knee: A Comparative Study of Traditional and Alternative Methods.

16. Mont, M.A., Jones L.C., Cordista A., Shuler M., Rajadhyaksha A.D., Glueck C., Hungerford D.S.: Identification of Total Joint Arthroplasty Patients at High Risk for Pulmonary Embolism.

17. Okubadehjo G., Rajadhyaksha A.D., Foran J., Mont, M.A., Jones L.C., Hungerford D.S.: Treating Osteoarthritis of the Knee: An Orthopaedist's Perspective.

18. Jones L.C., Mont, M.A., Perez O., Rajadhyaksha A.D., Hungerford D.S.: Procrit Therapy

for Total Joint Arthroplasty.

19. Mont, M.A., Rajadhyaksha A.D., Domb B., Jones L.C., Hungerford D.S.: Outcomes of Limited Femoral Head Resurfacing as Compared to Total Hip Arthroplasty for Osteonecrosis.

20. Rajadhyaksha A.D., Perez O., Etienne G., Khanuja H., Mont, M.A., Hungerford D.S.: Outcomes of Limited Resurfacing for Osteonecrosis of the Femoral Head.

21. Rajadhyaksha A.D., Foran J., Mont, M.A., Lennox D.W., Hungerford D.S.: Outcomes of Total Hip Arthroplasty in Patients 21 Years of Age or Younger.

22. Shuler M.S., Rajadhyaksha A.D., Mont, M.A., Jones L.C., Hungerford D.S.: A Cost Comparison Study of Patients Receiving Six Weeks of Intravenous Antibiotics after an Infected Total Knee Replacement, Treated at Home or in a Hospital Setting.

23. Foran J., Rajadhyaksha A.D., Mont, M.A., Jones L.C., Hungerford D.S.: Outcomes of Total Knee Arthroplasty in Obese Patients.

24. Mont, M.A., Rajadhyaksha A.D., Etienne G., Jones L.C.: Outcomes of Nonvascularized Bone Grafting for Osteonecrosis of the Femoral Head.

ABSTRACTS SUBMITTED TO AAOS – 2003:

1. Kirby H., Hoeman T., Moskal J., Schurman J., Greene K., McCarthy J., Rajadhyaksha A.D., Belisle A., Mont, M.A.: Anthropometric Measurements of the Human Knee: Correlation to Sizing of Existing Knee Arthroplasty Systems.

2. Mears S., Bawa M., Rajadhyaksha A.D., Jones L.C., Hungerford D.S., Mont, M.A.: Shortened Hospital Stays after Total Knee Arthroplasties Have No Effect on Decreased Complication Rates.

3. Mears S., Bawa M., Jones L.C., Rajadhyaksha A.D., Hungerford D.S. Mont, M.A.: Shortened Hospital Stays after Total Hip Arthroplasties Have No Effect on Decreased Complication Rates.

4. Baumgarten K., Mont, M.A., Etienne G., Rajadhyaksha A.D., Jones L.C., Hungerford D.S., Bluemke D.: The Prognostic Value of Magnetic Resonance Imaging for Avascular Necrosis of the Knee.

5. Rajadhyaksha A.D., Foran J., Hozack W., Rothman R., Stiehl J., Hungerford M., Manoso M., Hungerford D.S., Mont, M.A.: Outcomes of Total Hip Arthroplasty in Patients 21 Years of Age or Younger.

6. Wenz J., Etienne G., Shaw J., Hungerford D.S., Mont, M.A.: Total Knee Arthroplasties for Patients with Extensor Mechanism Deficiency.

7. Rajadhyaksha A.D., Delanois R., Etienne G., Hungerford D.S., Mont, M.A.: Atraumatic Avascular Necrosis of the Distal Tibia.

8. Rajadhyaksha A.D., Etienne G., Jones L.C., Mont, M.A.: Location of Intra-Articular Injections of the Knee Affects Pain Levels.

9. Shuler M., Rajadhyaksha A.D., Jones L.C., Hungerford D.S., Mont, M.A., Etienne G.: A Cost Comparison Study of Patients Receiving Intravenous Antibiotics after an Infected Total Hip Replacement: Treatment at Home versus the Hospital Setting.

10. Rajadhyaksha A.D., Gordon N., Etienne G., Jones L.C., Mont, M.A.: A Review of Classification Methods for Avascular Necrosis (AVN) Allows for Cross Study Outcome Evaluation.

11. Tortolani P.J., Perez O., McCarthy E., Rajadhyaksha A.D., Hungerford D.S., Mont, M.A.: Rapidly Progressive Hip Disease: Demographic, Histopathologic, and Radiographic Aspects.

12. Mont M.A., Bhave A., Rajadhyaksha A.D., Etienne G., Starr R.: Gait Analysis of Metal-on-Metal Surface Arthroplasty: A Comparison Study to Matched Osteoarthritic and Standard Total Hip Replacements.

13. Rajadhyaksha A.D., Etienne G., Mont, M.A., Jones L.C.: Outcome of Nonvascularized Bone Grafting for Avascular Necrosis of the Femoral Head.

14. Mears S., Mont, M.A., Hixon J.C., Jones L.C., Hungerford D.S.: Spontaneous Osteonecrosis of the Knee is not a True Osteonecrotic Condition.

15. Perez O., Rajadhyaksha A.D., Moskal J., Hozack W., Teeny S., Steinberg M., Stiehl J., Hungerford D.S., Mont, M.A.: Femoral Stem Fractures after Total Hip Arthroplasty.

16. Rajadhyaksha A.D., Gordon N., Badra M., Jones L.C., Etienne G., Mont, M.A.: Scientific Rationale for the Surgical Treatment of Osteonecrosis.

17. Waldman B., Rajadhyaksha A.D., Etienne G., Mont, M.A.: Use of the Femoral Component with Antibiotic Impregnated Cement as a Spacer in the Treatment of Infected Total Hip Arthroplasty.

18. Gordon N., Rajadhyaksha A.D., Schnell J., Jones L.C., Hungerford D.S., Mont, M.A.: Clinical and Radiographic Outcomes of Total Knee Arthroplasty in High Activity Patients Compared to Non-High Activity Patients.

19. Foran J., Rajadhyaksha A.D., Jones L.C., Etienne G., Hungerford D.S., Mont, M.A.: A Comparison of Obese and Non-Obese Patients Who Underwent a Third Generation PCL Retaining Total Knee Arthroplasty.

20. Waldman B., Etienne G., Rajadhyaksha A.D., Mont, M.A.: Infected Total Knee Arthroplasty: A Metaanalysis.

21. Mont, M.A., Hostin E., Rajadhyaksha A.D., Jones L.C., McCarthy E., LaPorte D., Hungerford D.S.: Correlation of the Pathology of Osteonecrosis of the Femoral Head to Risk Factors, Radiographic Parameters, and Outcomes.

22. Jones L.C., Perez O., Rajadhyaksha A.D., Hungerford D.S., Mont, M.A.: Procrit Therapy for Total Joint Arthroplasty.

23. Schuler M., Rajadhyaksha A.D., Mont, M.A., Jones L.C., Hungerford D.S.: Cost Comparison of Intravenous Antibiotics: Administered at Home versus a Hospital Setting.

24. Mont, M.A., Waldman B., Rajadhyaksha A.D., Etienne G., Hungerford D.S.: Retaining Infected Total Knee Arthroplasty Components with Irrigation and Debridement.

25. Baumgarten K., Mont, M.A., Etienne G., Rajadhyaksha A.D., Hungerford D.S.: Atraumatic Osteonecrosis of the Knee in Patients Fifty-Five Years of Age and Older.

26. Jones L.C., Mont, M.A., Le T.B., Petri M., Glueck C., Hungerford D.S.: Coagulopathies: A Risk Factor in the Development of Avascular Necrosis.

27. Foran J., Rajadhyaksha A.D., Okubadejo G., Jones L.C., Hungerford D.S., Mont, M.A.: Treating Osteoarthritis of the Knee: A Comparative Study of Traditional and Alternative Methods.

28. Okubadejo G., Rajadhyaksha A.D., Foran J., Jones L.C., Hungerford D.S., Mont, M.A., Etienne G.: Treating Osteoarthritis of the Knee: An Orthopaedist's Perspective.

29. Rajadhyaksha A.D., Etienne G., Jones L.C., Mont, M.A.: Location of Intra-Articular Injections of the Knee Affects Pain Levels.

30. Gordon N., Badra M., Rajadhyaksha A.D., Etienne G., Jones L.C., Mont, M.A.: A Review of Classification Methods for Avascular Necrosis (AVN) Allows for Cross Study Outcome Evaluation.

31. Etienne G., Waldman B., Rajadhyaksha A.D., Mont, M.A.: Use of a Functional Temporary Prosthesis in Two-Stage Approach to Infected Total Hip Arthroplasty.

32. Gordon N., Rajadhyaksha A.D., Badra M., Etienne G., Schmalzried T., Jones L.C., Mont, M.A.: Scientific Rationale for the Surgical Treatment of Osteonecrosis.

33. Khanuja H., Rajadhyaksha A.D., Etienne G., Hungerford M., Jones L.C., Hungerford D.S., Kazmarek C., Mont, M.A.: Avascular Necrosis of the Knee: A Comprehensive Review.

ABSTRACTS SUBMITTED TO AAOS – 2004:

1. Baumgarten K., Mont, M.A., Etienne G., Hungerford D.S.: Atraumatic Secondary Osteonecrosis of the Knee in Patients 55 Years of Age and Older.

2. Mont, M.A., Gordon N., Etienne G., Jones L.C.: Classification Methods for Avascular Necrosis of the Hip Allows for Cross Study.

3. Mont, M.A., Gordon N., Jones L.C., Hungerford D.S., Etienne G.: Clinical and Radiographic Outcome in High Activity Patients Compared to Non-High Activity Patients.

4. Shimmin A., Miller R., Mont, M.A.: Clinical Experience with Osteogenic Protein-1 for the Treatment of Recalcitrant Long Bone Nonunions.

5. Delanois R., Naylor R.W., Mont, M.A., Etienne G., Romash M.M.: High Tibial Osteotomy Using Distraction Callotasis with Unilateral External Fixator.

6. Waldman B., Mont, M.A., Etienne G.: Infected Total Knee Arthroplasty: Defining This Condition and Treatment with Metaanalysis.

7. Bonutti P.M., McMahon M., Mont, M.A.: Limited Approach Total Knee Arthroplasty: A Comparison Study.

8. Bonutti P.M., McMahon M., Mont, M.A.: Minimally Invasive Total Knee Arthroplasty: Two Year Follow-up.

9. Mont, M.A., Jones L.C., Perez O.A., Etienne G., Hungerford D.S.: Procrit Therapy for Total Joint Arthroplasty.

10. Baumgarten K., Mont, M.A., Etienne G., Ragland P.S., Jones L.C., Hungerford D.S., Bluemke D.: The Prognostic Value of Magnetic Resonance Imaging for Avascular Necrosis of the Knee.

11. Perez O.A., Tortolani J., Etienne G., McCarthy E., Jones L.C., Hungerford D.S., Mont, M.A.: Rapidly Progressive Hip Disease: Demographic, Histopathologic, and Radiographic Aspects.

12. Mont, M.A., Gordon N., Badra M., Etienne E., Schmalzried T., Jones L.C.: Scientific Rationale for the Surgical Treatment of Hip Osteonecrosis.

13. Mears S., Mont, M.A., Hixon J.C., Jones L.C., Hungerford D.S., Etienne G.: Spontaneous

Osteonecrosis of the Knee is Not a True Osteonecrotic Condition.

14. Foran J., Okubadejo G., Jones L.C., Hungerford D.S., Etienne G., Mont, M.A.: Treating Osteoarthritis of the Knee: An Orthopaedist's Perspective.

15. Mont, M.A., He D.Y., Jones L.C., Hoffman K.C., Hungerford D.S., Zizic T.M.: The Use of Electrical Stimulation to Avoid Total Knee Arthroplasty.

16. Bonutti P.M., McMahon M., Mont, M.A.: The Use of the Suspended Leg, Minimally Invasive Technique for Total Knee Arthroplasty.

17. Etienne G., Mont, M.A., Ragland P.S., Waldman B.J.: Different Types of Spacers Used in the Two-Stage Treatment of Infected Total Knee Arthroplasty.

18. Bonutti P.M., McMahon M., Mont, M.A.: Minimally Invasive Total Knee Arthroplasty.

19. Khanuja H., Jones L.C., Hungerford D.S., Etienne G., Ragland P.S., Mont, M.A.: Osteonecrosis of the Shoulder.

20. Mont, M.A., Etienne G., Patel T., Friedlaender G., Cook S., Downey K., Shimmin A.: An Overview of the Use of the Bone Morphogenetic Protein, OP-1, for Musculoskeletal Applications.

21. Etienne G., Mont, M.A., Ragland P.S., Paley D., Stuchin S.A., Parvizi J.: Treatment Options for Monocompartmental Osteoarthritis of the Knee.

22. Etienne G., Mont, M.A., Ragland P.S.: Use of Constrained Acetabular Liners in Total Hip Arthroplasty.

ABSTRACTS SUBMITTED FOR AAOS – 2005:

1. Baumgarten K., Mont, M.A., Etienne G., Hungerford D.S.: Atraumatic Secondary Osteonecrosis of the Knee in Patients 55 Years of Age and Older.

2. Mont, M.A., Gordon N., Etienne G., Jones L.C.: Classification Methods for Avascular Necrosis of the Hip Allows for Cross Study.

3. Shimmin A., Miller R., Mont, M.A.: Clinical Experience with Osteogenic Protein-1 for the Treatment of Recalcitrant Long Bone Nonunions.

4. Delanois R., Naylor R.W., Mont, M.A., Etienne G., Romash M.M.: High Tibial Osteotomy Using Distraction Callotasis with Unilateral External Fixator.

5. Mont, M.A., Jones L.C., Perez O.A., Etienne G., Hungerford D.S.: Procrit Therapy for Total Joint Arthroplasty.

6. Baumgarten K., Mont, M.A., Etienne G., Ragland P.S., Jones L.C., Hungerford D.S., Bluemke D.: The Prognostic Value of Magnetic Resonance Imaging for Avascular Necrosis of the Knee.

7. Perez O.A., Tortolani J., Etienne G., McCarthy E., Jones L.C., Hungerford D.S., Mont, M.A.: Rapidly Progressive Hip Disease: Demographic, Histopathologic, and Radiographic Aspects.

8. Mont, M.A., Gordon N., Badra M., Etienne G., Schmalzried T., Jones L.C.: Scientific Rationale for the Surgical Treatment of Hip Osteonecrosis.

9. Mears S., Mont, M.A., Hixon J.C., Jones L.C., Hungerford D.S., Etienne G.: Spontaneous Osteonecrosis of the Knee is Not a True Osteonecrotic Condition.

10. Foran J., Okubadejo G., Jones L.C., Hungerford D.S., Etienne G., Mont, M.A.: Treating Osteoarthritis of the Knee: An Orthopaedist's Perspective.

11. Bonutti P.M., McMahon M., Mont, M.A.: The Use of the Suspended Leg, Minimally Invasive Technique for Total Knee Arthroplasty.

12. Bonutti P.M., Mont, M.A., Ragland P.S., McMahon M., Kazmarek C.M.: Minimally Invasive Revision Total Knee Arthroplasty.

13. Etienne G., Mont, M.A., Ragland P.S., Waldman B.J.: Different Types of Spacers Used in the Two-Stage Treatment of Infected Total Knee Arthroplasty.

14. Khanuja H., Jones L.C., Hungerford D.S., Etienne G., Ragland P.S., Mont, M.A.: Osteonecrosis of the Shoulder.

15. Etienne G., Mont, M.A., Ragland P.S., Paley D., Stuchin S.A., Parvizi J.: Treatment Options for Monocompartmental Osteoarthritis of the Knee.

16. Etienne G., Mont, M.A., Ragland P.S.: Use of Constrained Liners in Total Hip Arthroplasty.

ABSTRACTS SUBMITTED TO AAOS – 2006:

1. Ragland, Mont, Marulanda, Delanois, Flowers: Use of a Proximally HA-Coated Taper Cementless Stem for Avascular Necrosis of the Hip.

2. Flowers, Ragland, Marulanda, Leadbetter, Mont: The Use of Injectable Hyaluronans for Osteoarthritis of the Knee.

3. Ragland, Etienne, Delanois, Marulanda, Mont: Outcome of Shoulder Resurfacing for Glenohumeral Arthritis.

4. Mont, Ragland, Bhave, Starr: Gait Analysis of Metal-on-Metal Surface Arthroplasty.

5. Perez, Moskal, Hozack, Teeny, Steinberg, Stiehl, Hungerford, Mont: Femoral Stem Fractures after Total Hip Arthroplasty.

6. Foran, Okubadejo, Jones, Hungerford, Ragland, Mont: Treating Osteoarthritis of the Knee: An Orthopaedist's Perspective.

7. Mont, Jones, Perez, Ragland, Hungerford: Procrit Therapy for Total Joint Arthroplasty.

8. Mont, Ragland, Marulanda: Location of Intra-Articular Injections of the Knee Affects Pain Levels.

9. Mont, Ragland, Marulanda, Delanois: Metal-on-Metal Resurfacing for Extra-Articular Deformities or Retained Hardware of the Proximal Femur.

10. Mont, Ragland, Marulanda, Delanois, Flowers: Core Decompression for Secondary Osteonecrosis of the Knee Using a Small-Diameter Drilling Technique.

11. Mont, Ragland, Jones, Gordon, Marulanda: Classification Methods for Avascular Necrosis of the Hip Allows for Cross Study Comparison.

12. Mont, Ragland, Marulanda, Delanois: Multiple Irrigation and Debridement with Retention of Components in Infected Total Knee Arthroplasty.

13. Bennett, Ragland, Saleh, Thongtrangan, Kuskowski, Cheng, Sharkey, Stiehl, Mont: Total Hip Arthroplasties: What Are the Reasons for Revision?

14. Ragland, Mont, Marulanda, Delanois: Use of a Metal-on-Metal Resurfacing Arthroplasty for Avascular Necrosis of the Hip.

15. Mont, Bhave, Delanois, Ragland: Does Ipsilateral Hip Dysfunction Cause Contralateral Knee Degeneration?

16. Mont, Bonutti, MaMahon, Ragland: Five Year Results with Second Generation Hydroxyapatite Coated Acetabulum Implant.

17. Mont, Bonutti, Ragland, McMahon: Minimally Invasive Revision Total Knee Arthroplasty.

18. Parvizi, Saleh, Ragland, Mont: Use of Antibiotic Cement in Primary Hip Arthroplasty: A Meta-Analysis.

19. Marulanda, Ragland, Mont, Delanois: Use of a Bipolar Sealer for Hemostasis in Total Knee Arthroplasty: A Comparison with a Matched Group.

20. Ragland, Marulandas, Mont, Flowers, Delanois: Use of a Bipolar Sealer Device for Hemostasis in Total Hip Arthroplasty.

21. Baumgarten, Mont, Ragland, Hungerford: Atraumatic Secondary Osteonecrosis of the Knee in Patients Fifty-Five Years of Age and Older.

22. Foran, Gbolohan, Hungerford, Mont, Marulanda: Treating Osteoarthritis of the Knee: A Comparative Study of Traditional and Alternative Methods.

23. Bonutti, Mont, McMahon, Marker: Kinematic Comparison of Bilateral Knee Arthroplasties by Midvastus vs. Subvastus Approach.

24. Stukenborg-Colsman, Mont, Ostermeier, Barisic, Winghagen, Wirth, Ragland: Clinical and Radiographic Radiological Results of a Modular Tibial Baseplate at 5 to 7 Years.

25. Kolisek, Nennette, Mont, Ragland: Comparison Study of Minimally Invasive Dual Incision vs. Posterolateral Approach in Hip Arthroplasty.

26. Bonutti, Naughton, Mont, Ragland: Ceramic-on-Ceramic Hip Arthroplasties: Effects of Cup Inclination on Revision Rates.

27. Bonutti, Mont, D'Antonio, Capello, Naughton, Ragland: Effects of Obesity Total Hip Arthroplasty Performed with Two Different Bearing Couples.

28. Bonutti, Mont, McMahon, Ragland: Minimally Invasive Total Knee Arthroplasty: Minimally Invasive Total Knee Arthroplasty: Pitfalls and Complications.

29. Bonutti, Mont, McMahon, Ragland: Bilateral Knee Arthroplasty: Comparison of a Standard vs. Contralateral Minimally Invasive Approach.

30. Bonutti, Mont, McMahon, Ragland: Arthroscopic AssistedTotal Knee Arthroplasty.

31. Marulanda, Ragland, Mont, Marquess, Moweri, Reese, Wilson, Marker: The Use of Closed-Suction Drains in Total Joint Arthroplasties.

PRESENTATIONS (NATIONAL AND INTERNATIONAL):

October 19, 1986 The Effect of Ultrasonic Stimulation on Fresh Fracture Repair in Rabbits Bioelectrical Repair and Growth Society. Utrecht, The Netherlands.

January 21, 1987 Application of a Culture System for Analysis of Differentiation and Mineralization of Mesenchymally Derived Cells. Orthopaedic Research Society. San Francisco, CA.

January 19, 1987	Ultrasonic Effects on Fresh Fracture Healing in Rabbits. Orthopaedic Research Society, San Francisco, CA.
March 17, 1988	Analysis of Differentiation and Mineralization in a Mesenchymally-Derived Culture System. American Orthopaedic Association, Resident's Conference, Boston, MA.
May 9, 1988	Effects of Ultrasonic Stimulation on Fresh Fracture Healing in Rabbits. New York Academy of Medicine, Section on Orthopaedic Surgery, New York, NY.
Feb. 10, 1990	Post-Operative Radiographic Parameters as Predictors of Clinical Outcome in Unstable Ankle Fractures. American Academy of Orthopaedic Surgeons, New Orleans, LA.
April 26, 1991	Total Knee Replacement after High Tibial Osteotomy, Annual Advances in Hip and Knee Arthroplasty. Williamsburg, VA.
April 26, 1991	Cementless Total Hip Replacement in Patients Less Than 45 Years of Age. Annual Advances in Hip and Knee Arthroplasty. Williamsburg, VA.
Sept. 3, 1991	Culture of Chondrocytes for Cartilage Repair, National Institutes of Health, Johns Hopkins University, Division of Geriatric Medicine and Gerontology. Baltimore, MD.
Feb. 18, 1992	Surgical Decompression for Peroneal Nerve Palsy Complicating Total Knee Arthroplasty. American Academy of Orthopaedic Surgeons, Washington, D.C.
May 1, 1992	Organ Response to Biomaterials - Total Knee Replacement. Symposium: Biological Response to Orthopaedic Implants, Baltimore, MD.
Nov. 14, 1992	Uncemented Total Hip Arthroplasty in Patients Less than 50 Years with Rheumatoid Arthritis. Association for Arthritic Hip and Knee Surgery Society, Dallas, Tx.
Dec. 4, 1992	Treatment of Avascular Necrosis of the Hip. The Peter Mack Memorial Lectureship, Baltimore, Maryland.
Dec. 12, 1992	Avascular Necrosis of the Hip. Surgical Ground Rounds, The Johns Hopkins University, Baltimore, Maryland.
Feb. 16, 1993	Total Knee Arthroplasty after Failed High Tibial Osteotomy: Long-Term Follow-Up and Results. American Acedemy of Orthopaedic Surgeons. New Orleans, LA.

Feb 18, 1993	Total Knee Arthroplasty after Failed High Tibial Osteotomy: Long-term Follow-Up and Results. Knee Society, New Orleans, L.A.
March 20,1993	Animal Models to Analyze the Implants. Symposium: Biological Response to Orthopaedic Implants, Baltimore, MD.
April 29, 1993	Isokinetic Concentric Versus Eccentric Training of Shoulder Rotators with Functional Evaluation of Performance Enhancement in Elite Tennis Players. USTA National Conference on Sports Medicine and Science in Tennis, Sonesta Beach Hotel, Key Buskin, Florida.
Sept. 23, 1993	New Perspectives on Joint Reconstruction. Rehabilitation Grand Rounds, The Johns Hopkins Medical Institutions, Baltimore, MD
Feb 16, 1994	Varus Osteotomy for Ischemic Necrosis of the Femoral Head results of a Long-Term Follow-Up Study. American Acad. Orth. Surgeons, New Orleans, LO.
April 16, 1994	Structural and Non-structural bone grafting in clinical orthopaedics. Symposium, Biological Response to Orthopaedic Implants. Stauffer Hotel, Inner Harbor, Baltimore, MD.
April 22, 1994	Total Knee Replacement Status Post High Tibial Osteotomy. Current Concepts in Total Joint Replacement. Westchester Marriott Hotel, Tarrytown, New York.
May 16, 1994	ABC Traveling Fellows Clinical Science Program. Co-director of program and presentation on "New Treatments for AVN." The Johns Hopkins University, Baltimore, Maryland.
October 15, 1994	Core Decompression for Avascular Necrosis of the Distal Femur: Long-Term Follow-up. ARCO 5th International Symposium on Bone Circulation. Hilton Head, South Carolina.
October 15, 1994	Core Decompression for Avascular Necrosis of the Femoral Head in SLE: Long-Term Report of Risk Factors for Progression. ARCO 5th International Symposium on Bone Circulation, Hilton Head, South Carolina.
Feb. 14, 1995	Core Decompression for Avascular Necrosis of the Distal Femur. American Acad. Orth. Surgeons, Orlando, Florida.
Feb. 19, 1995	The Natural History of the Contralateral Knee after Primary Knee Arthroplasty for Osteoarthritis. Knee Society, Orlando, Florida.

May 19, 1995	Avascular Necrosis of the Hip: Fifth Annual Current Concepts in Orthopaedics. Southern Orthopaedic Association, Harbor Court Hotel, Baltimore, Maryland.
August 25, 1995	Treatment of Osteonecrosis of the Hip: First Annual Osteonecrosis Research Symposium. Baltimore, Maryland.
October 5, 1995	The Trapdoor Procedure Using Cortical and Cancellous Bone Grafting for Osteonecrosis of the Femoral Head. Association Research Circulation Osseous, Vienna, Austria.
October 7, 1995	Core Decompression for Recalcitrant Transient Osteopenia of the Hip. Association Research Circulation Osseous, Vienna, Austria.
Nov. 6, 1995	New Treatment Methods for Osteonecrosis. Grand Rounds, The Johns Hopkins Orthopaedic Department, Baltimore, Maryland.
Nov. 11, 1995	Histology of bone marrow edema syndrome and avascular necrosis of the hip. Union Memorial Hospital Bone Symposium, Baltimore, Maryland.
Dec. 15, 1995	New treatments for avascular necrosis. Surgery Grand Round, The Johns Hopkins University. Baltimore, Maryland.
Feb. 20, 1996	Bilateral Knee Replacement. Switzerland Howmedica Regional Meeting, New York, New York.
Feb. 26, 1996	Core decompression for avascular necrosis of the distal femur. Long-term follow-up. American Academy Orthopaedic Surgeons Annual Meeting. Atlanta, Georgia
April 11, 1996	New concepts in the treatment of avascular necrosis of the hip. Joint Reconstruction Lecture Series. Rothman Institute, Philadelphia, Pennsylvania.
April 13, 1996	Bone Grafting. Biological Response To Orthopaedic Implants. Johns Hopkins Medical Institutions, Stauffer Renaissance Harborplace Hotel, Baltimore, Maryland.
May 2-3, 1996	Current concepts of the Knee. 3rd Annual Symposium. New York Medical College, Valhalla, New York. a. Thursday, May 2nd: Biologic Restoration of Articular Cartilage b. Thursday, May 2nd: Osteonecrosis of the Knee c. Thursday, May 2nd: Management of Infected Total Knee Arthroplasty. Sequential Debridement d. Thursday, May 2nd: Periprosthetic Fracture

July 27, 1996	Particle Disease in Total Hip Replacement at Total Hip Arthroplasty Stem Fixation in Total Hip Replacement. Turf Valley Hotel and Country Club. Ellicott City, Maryland.
Sept. 21, 1996	Basic Science Course: Biomechanics of the Hip. The Johns Hopkins University, Baltimore, Maryland.
October 2-5,1996	Harris Hip Course: Total Hip Arthroplasty: Molded vs. Machined Polyethyline: Clinical Data. Boston, Massachusetts.
Oct. 19, 1996	Avascular necrosis - New Treatment Methods. American College of Rheumatology Annual Meeting, Orlando, Florida
Nov. 9, 1996	American Orthopaedic Association; Shoulder and Ankle Osteonecrosis - International Symposium "The Etiology, Diagnosis and Management of Osteonecrosis of the Human Skeleton." Durham, North Carolina
Dec. 6, 1996	Avascular Necrosis - Latest concepts on treatment and pathophysiology - Forum Club, Baltimore, Maryland.
Feb. 15, 1997	"Multiple Irrigation and Débridement and Retention of Components in Infected TKA - American Academy of Orthopaedic Surgeons, San Francisco, California
Feb. 16, 1997	Presentation of "Multiple Irrigation and Débridement and Retention of Components in Infected Total Knee Arthroplasty. - Knee Society San Francisco, California.
May 8-9, 1997	Symposium: Current Concepts in Hip Trauma and Reconstructive Hip Surgery. Tarrytown House, Tarrytown, New York. a. Introduction to Avascular Necrosis b. Non-vascularized Bone Grafting c. Limited Femoral Resurfacing
June 27, 1997	Symposium on Osteonecrosis: Limited Femoral Resurfacing Sponsored by Wright-Medical, Inc., Baltimore, Maryland a. Basic Science, New Concepts of Pathophysiology, Non-operative Treatment Methods. b. Limited Femoral Resurfacing c. Non-vascularized bone grafting
Sept. 4, 1997	Salvage Procedures for Complex Soft Tissue Defects Around the Knee. Knee Society Interim Meeting, Waldorf Astoria Hotel, New York,New York.

Sept. 19, 1997 A Canine Defect Model Treated with Osteogenic Protein-1, 2nd International Osteogenic Protein-1 Conference. The Exchange Conference Center, Boston, MA.

Sept. 27, 1997 Early Fall Clinical Course Total Joint Arthroplasty: Current Issues, Concepts and Considerations. Four Seasons Resort, Palm Beach, Florida.
1. Basic Science, New Concepts of Pathophysiology and Non-operative Treatment Methods.
2. Limited Femoral Resurfacing Arthroplasty.

October 4-6, 1997 ARCO International Meeting - 8th International Symposium on Bone Circulation: Various Osteonecrosis Talks, St. Thomas' Hosptial, London, United Kingdom.
1. Multifocal osteonecrosis.
2. Osteonecrosis of the ankle.
3. Limited Femoral Resurfacing Arthroplasty.
4. Non-vascularized bone grafting for femoral head osteonecrosis.
5. 15-year experience with femoral head resurfacing.
6. Metal on metal hip prosthesis.

Dec. 4-6, 1997 Total Knee Forum. "Soft-tissue Ligament Balancing in Revision Total Knee Artrhoplasty." Millennium Broadway Hotel. New York, New York.

Jan, 1998 Wright Medical Current Concepts Course, Denver Colorado.
1. Limited Femoral Resurfacing for Osteonecrosis.
2. Acetabular Revision Hip Arthroplasty.

March 16, 1998 Orthop. Res. Society: "Femoral Head Defect Model: Treatment with Strut Autografting with and without Osteogenic Protein-1. New Orleans, Louisiana.

March 19, 1998 Operative Treatment Methods for Osteonecrosis of the Hip. In Instructional Course #124. "Understanding and Treating Osteonecrosis". New Orleans, Louisiana.

March 20, 1998 Discussion of Paper #128, "Functional Outcome of Total Hip Arthroplasty after Pelvic Osteotomy" and #129. "Activity of total joint replacement patients." New Orleans, Louisiana.

March 21, 1998 "Osteonecrosis in Inflammatory Arthritis" Instructional Course #321; "Surgical Management of Inflammatory Arthritis of Adult Hip and Knee." American Academy of Orthopaedic Surgeons. New Orleans, Louisiana.

March 23, 1998 "Evidence of Inappropriate Application of Autologous Cartilage Transplantation theory in an Uncontrolled Environment. Am. Acad. Orthop. Surgeons. New Orleans, Louisiana.

May 1-2, 1998	Fourth Symposium on Biological Response to Orthopedic Implants. Moderator of Implants/Approaches for Nerve Tissue Repair in Orthopaedics. Treatment with Osteonecrosis Bone Morphogenetic Proteins". Stauffer Renaissance Harbor Place Hotel, Baltimore, Maryland
May 4, 1998	New Techniques for Cartilage Resurfacing, Surgical Grand Rounds, Greater Baltimore Medical Center, Maryland
May 22, 1998	New Treatments for Osteonecrosis. Presentation to ASEAN Traveling Fellows. Baltimore, Maryland
June12-13, 1998	Wright Medical AVN Course. Hilton, Sonoma Valley, California 1. Ligament Balancing in Total Knee Replacement. 2. Multiple Irrigation and Debridement for Infected Total Knee Replacement.
July 16, 1998	"Acetabular Revisions." Orthopaedic Grand Rounds, Baltimore, Maryland.
July 24, 1998	Symposium 1998 Avascular Necrosis Mini-Course, Baltimore, Maryland. Moderator and Contributed 6 Talks.
Aug 21-22, 1998	New Horizons in Joint Disease Conference. Talk on "Cytokines Management" and "Management of infected prosthesis". Sydney, Australia
Aug 28, 1998	Evolving Technologies and Techniques in Total Joint Replacement. Talk on Limited Femoral Reconstruction for Osteonecrosis of the Femoral Head. Denver, Colorado
Sep. 10-15,1998	7th Annual Baltimore Limb Deformity Course. Talk on "Total Knee and Hip Replacement in the Face of Malalignment." Baltimore, Maryland.
Sep. 28, 1998	Chesapeake Health Education Program, Inc. Symposium on "Total Joint Replacement". Perry Point, Maryland. (Moderator)
Oct. 14-18, 1998	Eastern Orthopaedic Association Meeting - AVN Current Concepts Talk on "Non-vascularized Grafting Procedures." San Juan, Puerto Rico.
Oct 29-30, 1998	Current Concepts of the Knee. Annual Symposium, New York Medical College, New York a. Osteonecrosis of the knee. b. Ligament Balancing in Total Knee Arthroplasty. c. Extraarticular Deformity of the Knee.
Feb 3, 1999	Wright Medical Annual Representatives Courses: "Conserve Now and You'll hip for later" Sutton Place Hotel, Irvine, California

Feb 6, 1999	American Academy of Orthopaedic Surgeons: Instructional Course: Understanding and Treating Osteonecrosis Of the Hip. “Classification and treatment of Osteonecrosis” Anaheim, California
Feb 11, 1999	Australian, East Asian Visiting Fellows Howmedica Symposium Osteonecrosis of the Hip. Baltimore, Maryland
April 21, 1999	Combined ARCO- SICOT Meeting Sydney, Australia 5 talks on osteonecrosis: A. Osteonecrosis of the Humeral Head: Treatment by Hemiarthroplasty B. Femoral Resurfacing Arthroplasty for Avascular Necrosis of the Femoral Head C. Multifocal Osteonecrosis - A Multicenter Study from the Collaborative Osteonecrosis Group D. Ostonecrosis of the Elbow E. Pathology of Core Decompression Specimens 3 talks:
May 6-7, 1999	Baptist Center for Medical Education: 1. Total Hip Replacement in the morbidly obese patient. 2. Surgical treatment of enigmatic thigh pain. 3. Osteonecrosis Current Concepts for treatment. Nashville, Tennessee
May 21, 1999	Total Knee Forum: (Sponsored by Stryker-Howmedica) A. Risk Factors in Primary Total Knee Arthroplasty B. Planning for Revision Knee Surgery Hyatt Regency Hotel, Washington, D.C.
June 3, 1999	Grand Rounds at Washington Medical Center: Avascular Necrosis of the Hip Washington, D.C.
June 12, 1999	The Johns Hopkins Orthopaedic Alumni Baer Lectureship Day. Talk on Osteonecrosis: Teatmentsfor the New Millenium. Baltimore, Maryland
June 22, 1999	The Johns Hopkins - Union Memorial National Review Course: “Osteonecrosis” Marriott Hotel, Baltimore, Maryland

July 27, 1999 Stryker-Howmedica-Osteonix Strategic Planning Meeting
Talk on Solution based problem of osteonecrosis.
Rutherford, New Jersey

August 4, 1999 AORTA Summer Meeting, Two Talks, Milwaukee, Wisconsin

August 14, 1999 Wright Medical National Sales Meeting: Point Counterpoint:
Resurfacing for osteonecrosis of the femoral head.

Sept 3, 1999 8th Annual Baltimore Limb Deformity Course. "Total Knee and Hip Replacement in the Face of Malalignment", Baltimore, Maryland.

Sept 16-18, 1999 Hip Society Interim Meeting: Talk on Resurfacing vs Total Hip Arthroplasty For Osteonecrosis of the Femoral Head. Cororado Hotel, San Diego, CA

Oct 1, 1999 Current Concepts of the Shoulder: Annual Symposium at New York Medical College.
"Shoulder Osteonecrosis" Valhalla, New York.

Oct 25-27, 1999 Society of Military Orthopaedic Surgeons, Session Moderator of Total Joint Arthroplasty, Lecture on Osteonecrosis, Williamsburg, Pennsylvania.

Oct 29-30, 1999 "International Symposium on Osteonecrosis, Seoul Korea.
1. Diagnostic modalities for osteonecrosis.
2. Various treatments comparison - its results comparison and pitfalls.

Nov 4-5, 1999 DeGroot Course Boston Massachusetts
1. Avascular Necrosis of the Femoral Head

Nov 9-12, 1999 Maryland Academy of Physician Assistants
Lecture on Osteonecrosis.

March 13-16, 2000 AAOS MEETING
INSTRUCTIONAL COURSES:
1. Osteonecrosis of the Hip.
2. Osteonecrosis of the Knee.
3. Surgical Treatment of Hip and Knee Inflammatory Arthritis.

March 18-19, 2000 KNEE SOCIETY MEETING
1. Use of stems for revision total knee arthroplasty.

April 14-15, 2000 ORTHOPAEDIC SURGICAL MANAGEMENT AND RESULTS 2000 (Total Hip and Knee Reconstruction). Las Vegas, Nevada
1. Improving metallurgy for cement and biologic fixation.
2. Ligament balance and stability in total knee arthroplasty.
3. Osteonecrosis of the knee: treatment options.

May 12-13, 2000 FELLOWS MEETING

1. Had 33 former Fellows join us in Baltimore for an excellent meeting. Letters are going out to plan for next year's meeting which perhaps can be expanded.
   Addendum: In addition, we'll try to pursue collaborative work with other key Fellows from other programs around the country.

June 14, 2000 University of Maryland Grand Rounds
Osteonecrosis of the Femoral Head

June 16, 2000 Johns Hopkins Orthopaedic Review Course
Avascular Necrosis

July 25, 2000 Hip Society Meeting Summer Meeting
Moderator
Boston, Massachusetts

August 1, 2000 AORTA
Lake Tahoe, Utah

1. Avascular Necrosis of the Femoral Head
2. Non-operative Treatment of Osteoarthritis of the hip
3. Database Planning

October 2, 2000 FLORIDA COURSE

1. New treatment for avascular necrosis of the hip
2. Hemi-Resurfacing Workshop

October 4-6, 2000 ARCO Meeting and International Symposium

1. Treatment Algorithm for Osteonecrosis

October 24, 2000 GRAND ROUNDS AT SINAI

1. Avascular necrosis of the hip

October 29, 2000 ZELICOFF COURSE

1. Metal on metal
2. Avascular necrosis of the hip

November 29, 2000 GRAND ROUNDS AT WASHINGTON, DC RHEUMATOLOGY SOCIETY

1. Avascular necrosis of the hip

January 11-15, 2001 WINTER COURSE IN BAHAMAS

1. Infected total knee arthroplasty
2. Avascular necrosis treatment

AUDIO/VIDEO/TV PRESENTATIONS:

1. Syndicated television video on strength training for tennis players. Multiple Local News Broadcasts (1993 - 1994).

2. Hip Anatomy: Hungerford, D.S., Mont, M.A., Hungerford, M.W., Video Journal of Orthopaedics, 1996.

3. Hemi-Resurfacing of the Hip. Mont, MA.

4. Hip and Knee Anatomy. Hungerford, D.S., Mont, M.A., Hungerford, M.W., Video Journal of Orthopaedics, 1996.

5. Total Hip Arthroplasty after Hip Fusion. Local Television (Baltimore) presentation. (Sept 15, 1997).

6. Resurfacing Arthroplasty for Femoral Head Osteonecrosis. Videotape of indications and surgical technique. Wright Medical Symposium, Baltimore, Maryland 1997.

7. Infection after Dental Procedures. Maryland Public Television (March 9, 1999).

PRESENT RESEARCH WORK:

Presently my major focus for clinical research has been on developing new methods for diagnosing and treating osteonecrosis. To this aim, we are studying;

(1) Coagulation parameters in terms of the pathophysiology of the disease.
(2) Limited MRI scanning to aid in diagnosis.
(3) Identifying risk factors for onset and progression in SLE and other high risk groups.
(4) Investigating various treatment methods in early stages of the disease.
    a. Pharmacological agents
    b. Core decompression with adjuvant growth factors (rhBMP2, OP-1, Grafton).
(5) Treatments aimed at later stages;
    a. Bone grafting
    b. Limited femoral resurfacing
(6) Diagnosis and outcomes for osteonecrosis of other joints (shoulder, knee, ankle).

With respect to basic science research, I have participated as the principal investigator in three areas;

    a. Characterizing the healing on a femoral head defect model in canines (with anxillary bone grafting and BMPs)
    b. Analyzing the pathology from femoral head specimens retrieved from patients with osteonecrosis.
    c. Studying the pathophysiology in relation to heritable thrombophilia and/or hypofibrinolysis.

Another major area of focus has been to evaluate those factors which may affect the successful outcome of clinical research in characterizing patients with total joint arthroplasties.

Basic Science Research on total hip replacement has focused on:

a. Polyethylene wear from cups manufactured with different methods.
b. Resistance to Activated protein C as a cause of pulmonary emboli.

Clinical research in total knee arthroplasty:

a. Various topics concerning infection treatment, diagnosis and associations.
b. Different designs and their effect on patello-femoral complications.
c. Characterization of unexplained or neuroma pain.

Basic Science of total knee arthroplasty:

a. Anatomy of extensor mechanism in relation to patellar wear patterns.
b. Alignment of femoral and tibial components.

Michael A. Mont 6/1/2017 Depositions and Trials

To the best of my recollection and based on information presently available to me, the following is a list of where I have given testimony over the past four years from June 1, 2013 to the present:

1. Heather Carter vs. Loucks:
    a. Deposition 9/10/2013 in Norfolk, Virginia
    b. Trial: 12/15/2015 in Denver, Colorado
2. Mingo vs. Depuy
    a. Deposition 4/2014 in Baltimore, Maryland
3. Judith Cherrak
    a. Deposition 5/8/2014 in Baltimore, Maryland
4. Branham vs. University Hospitals
    a. Deposition 6/2015 in Cleveland, Ohio
5. Gabel vs. Molloy
    a. Trial approximately 6/2015 in Cleveland, Ohio
6. Russo vs. Stamford Health Systems
    a. Deposition – 10/11/2015 in Baltimore, Maryland
7. Smith vs. Moskowitz
    a. Trial 10/2015 in Washington D.C.
8. Shanahan vs. Drinkwater
    a. Trial 11/18/2015 in Rochester, New York
9. Boyd vs. Sydney
    a. Deposition 10/15/2015 in Baltimore, Maryland
    b. Trial 2/22/2016 in Baltimore, Maryland
10. Wade vs. Gardner
    a. Deposition 01/10/2016 in Fairfax, Virginia
11. McNally vs. Hur
    a. Deposition 8/2016 in Cleveland, Ohio

Sources of Heat in Operating Room

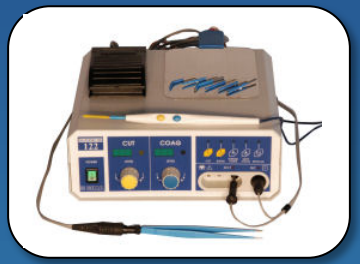
Lights

Monitors

Anesthesia Equipment

Drills and Saws

Surgical Staff



Electrocautery and Other Equipment

Patient

HEPA Filters Do Not Affect Infection Rates following Primary Total Joint Arthroplasty with Forced Air Warmers

Curtis GL, Faour M, Klika AK, Barsoum WK, Higuera CA

Background: Forced-air warmers (FAW) have been used effectively to prevent hypothermia, but some studies have suggested that FAW may increase bacterial contamination of the surgical site. To address this, a new generation of FAW with high efficiency particulate air filters (FAW-HEPA) were introduced. This study compared infection rates following total joint arthroplasty (TJA) procedures using FAW and FAW-HEPA.

Methods: Patients who underwent primary TJA at a large academic center and two high-volume arthroplasty regional hospitals within a single healthcare system were retrospectively reviewed. In 2014, the hospital system switched from FAW (3M, St. Paul, MN) to FAW-HEPA (Stryker, Kalamazoo, MI). A total of 5,405 TJA cases in 2013 and 2015 were identified. Patients in 2013 (n=2,792) had procedures with FAW, while patients in 2015 (n=2,613) had procedures with FAW-HEPA. The primary measured outcome was the incidence of infection within 90 days of surgery. Prosthetic joint infection (PJI) was defined as reoperation with arthrotomy or meeting MSIS criteria for PJI. Surgical site infection (SSI) was defined as a wound complication treated with antibiotics or irrigation and debridement. The χ^2-test was used for univariate analysis, while logistic regression models were adjusted for age, gender, comorbidities, BMI, and operative time.

Results: The groups had no differences in demographics or comorbidities, but operative time was significantly longer in the FAW-HEPA group (111 min vs 108 min; Table 1, p=0.001). The FAW group had a higher rate of SSI (n=33 [1.18%] vs. n=22 [0.84%]; Table 2, p=0.21), but a lower rate of PJI than the FAW-HEPA group (n= 13 [0.47%] vs. n=20 [0.77%]; Table 2, p=0.15). The regression model did not show FAW to be an independent risk factor for infection. FAW did not significantly increase the risk of SSI (Table 3, OR=1.47; 95% CI0.83 –2.58; p=0.18), PJI (OR=0.53; 95% CI 0.25–1.13; p=0.09), or total infection (Table 3, OR=1.00; 95% CI 0.65–1.57; p=0.97).

Discussion: No statistically significant differences in SSI and PJI were found between FAW and FAW-HEPA use during TJA. Although studies have suggested that FAW increase infection risk, this study found no clinical difference.

Conclusions: FAW devices are not correlated to a higher risk of infection during TJA when compared to devices with HEPA filters.

Table 1. Comparison of patient demographics

Demographics TJA (n = 5,405)	FAW[a] n = 2,792	FAW-HEPA[b] n = 2,613	p-value
Age, Mean ± SD	63.2 ± 11.1	62.8 ± 11.3	0.19
Gender, Male (%)	1,224 (43.8)	1,206 (46.2)	0.08
Charlson Comorbidity Index, Mean ± SD	3.72 ± 1.99	3.70 ± 2.04	0.76
Body Mass Index, Mean ± SD	31.8 ± 6.8	32.0 ± 7.1	0.22
Operative Time, minutes, Mean ± SD	108 ± 37	111 ± 37	0.001

[a]Forced-air warmer
[b]Forced-air warmer with high efficiency particulate air filter

Table 2. Univariate analysis

Outcomes (%) TJA (n = 5,405)	FAW[a] n = 2,792	FAW-HEPA[b] n = 2,613	p-value
Surgical Site Infection (%)	33 (1.18)	22 (0.84)	0.21
Periprosthetic Joint Infection (%)	13 (0.47)	20 (0.77)	0.15
Total infection (%)	46 (1.65)	42 (1.61)	0.90

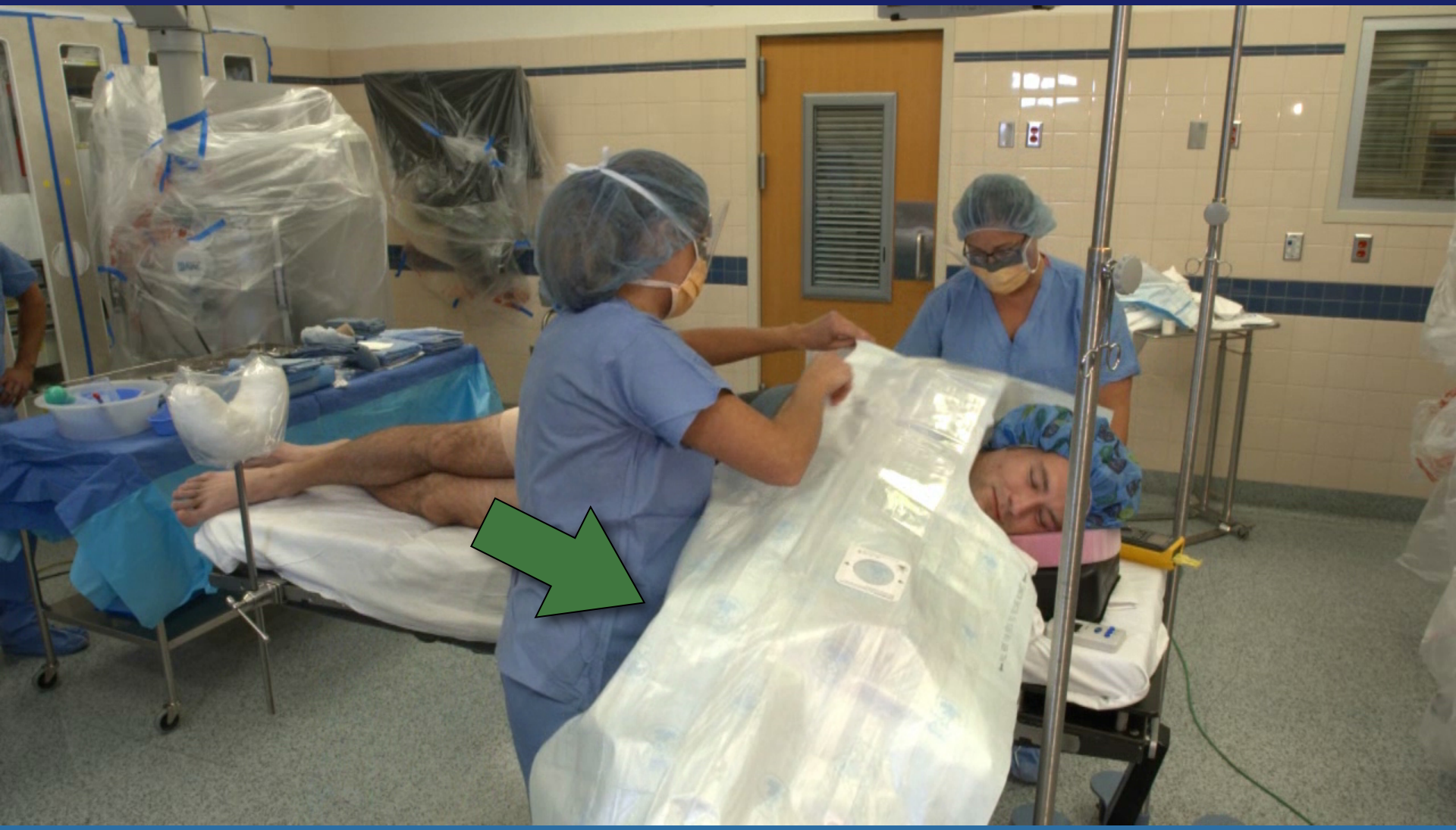
[a]Forced-air warmer
[b]Forced-air warmer with high efficiency particulate air filter

Table 3. Multivariate analysis

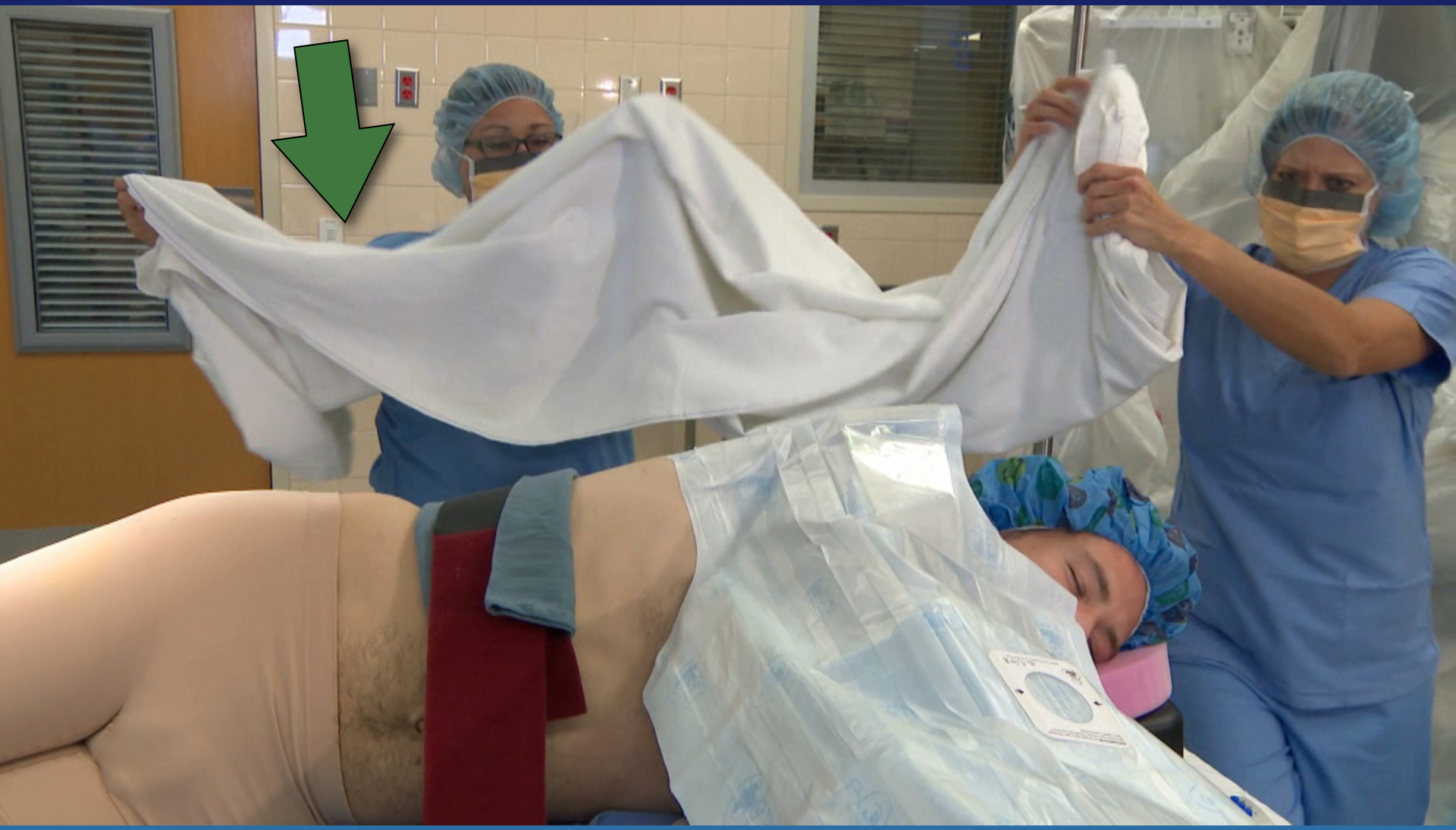
Total Joint Arthroplasty	Odds Ratio (95% Confidence Interval)	p-value
Surgical Site Infection	1.47 (0.83 – 2.58)	0.18
Periprosthetic Joint Infection	0.53 (0.25 – 1.13)	0.09
Total infection	1.00 (0.65 – 1.57)	0.97

FAW-HEPA used as reference
Factors adjusted for in the logistic regression model: Age, Gender, Charlson Index Score, Body Mass Index, and Operative Time.

Bair Hugger Blanket



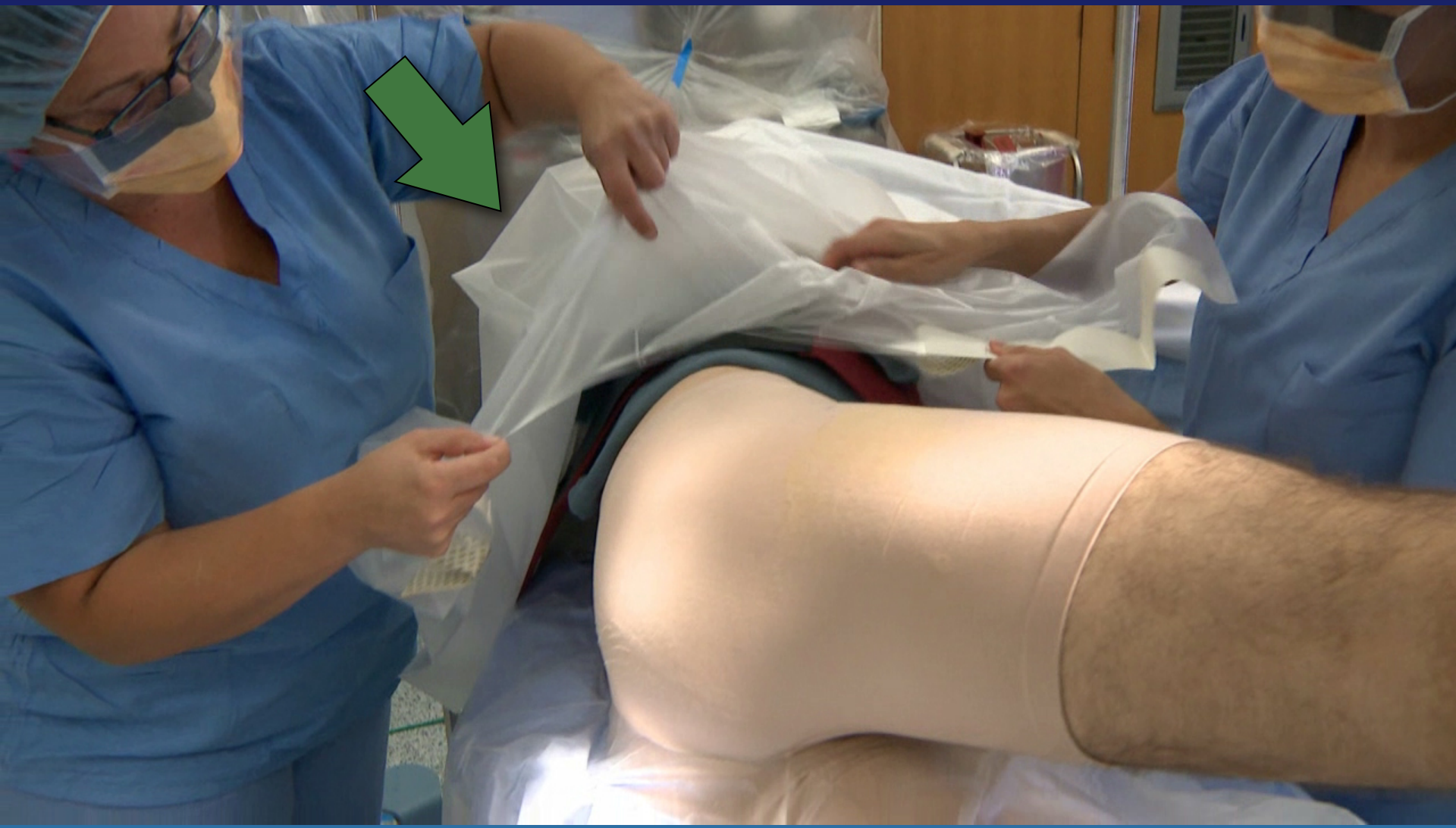
Cotton Blanket Over Bair Hugger Blanket



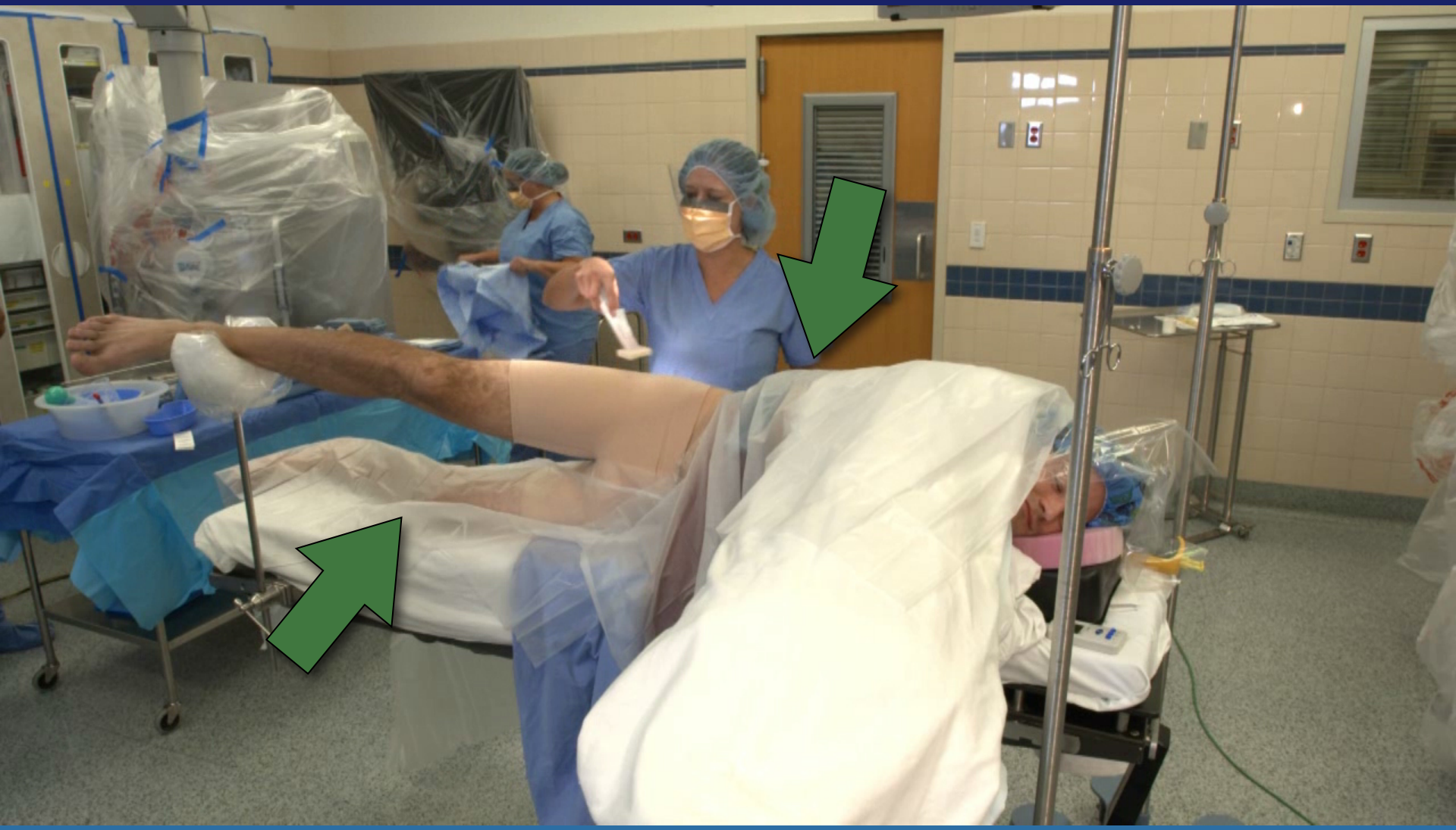
See-Through Drape Over Patient's Head

Clear Plastic Drape – Under Right Leg and on to the Left Leg

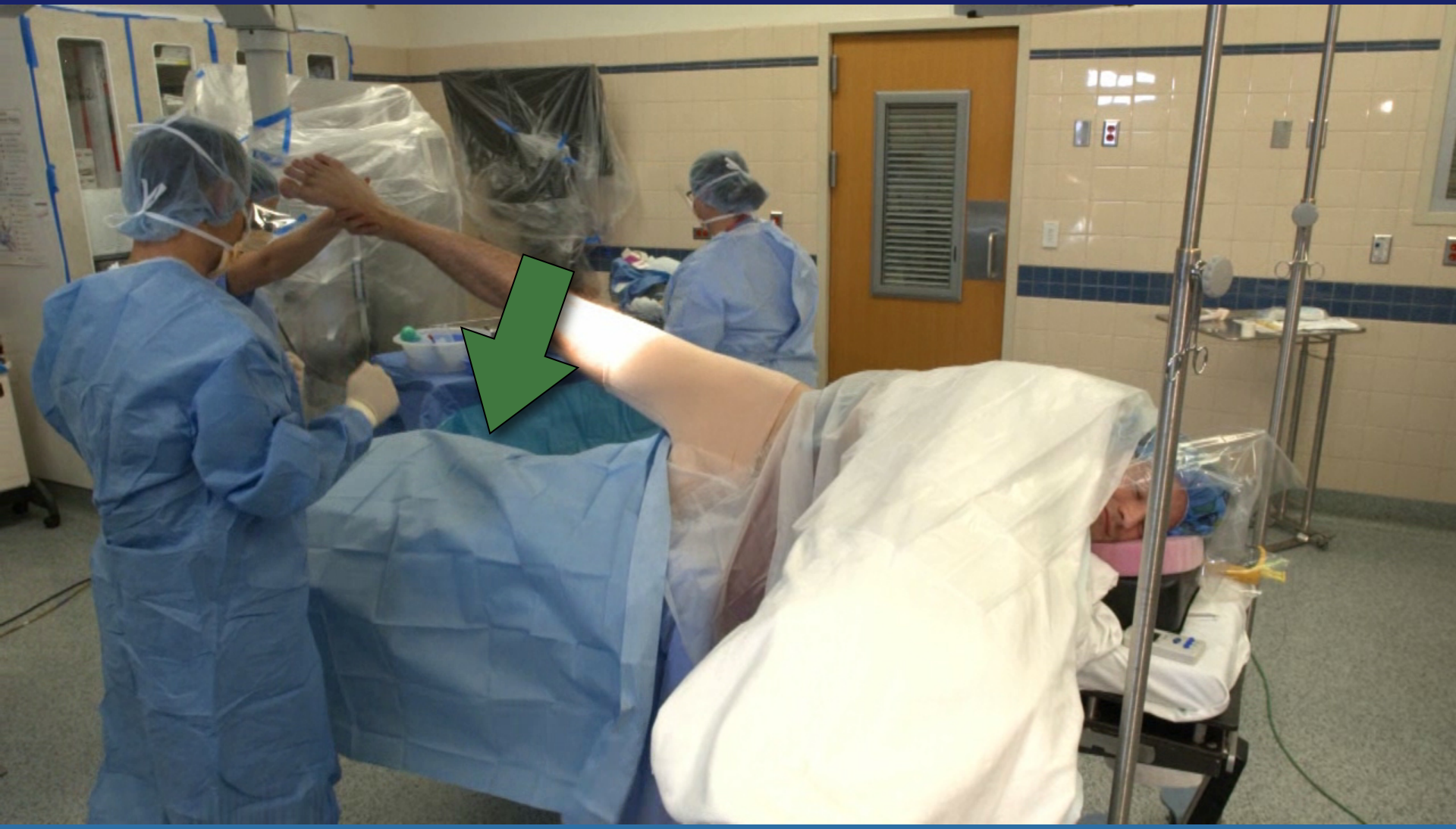
Clear Plastic Drape Above Waist



Clear Plastic Drapes Above and Below Waist

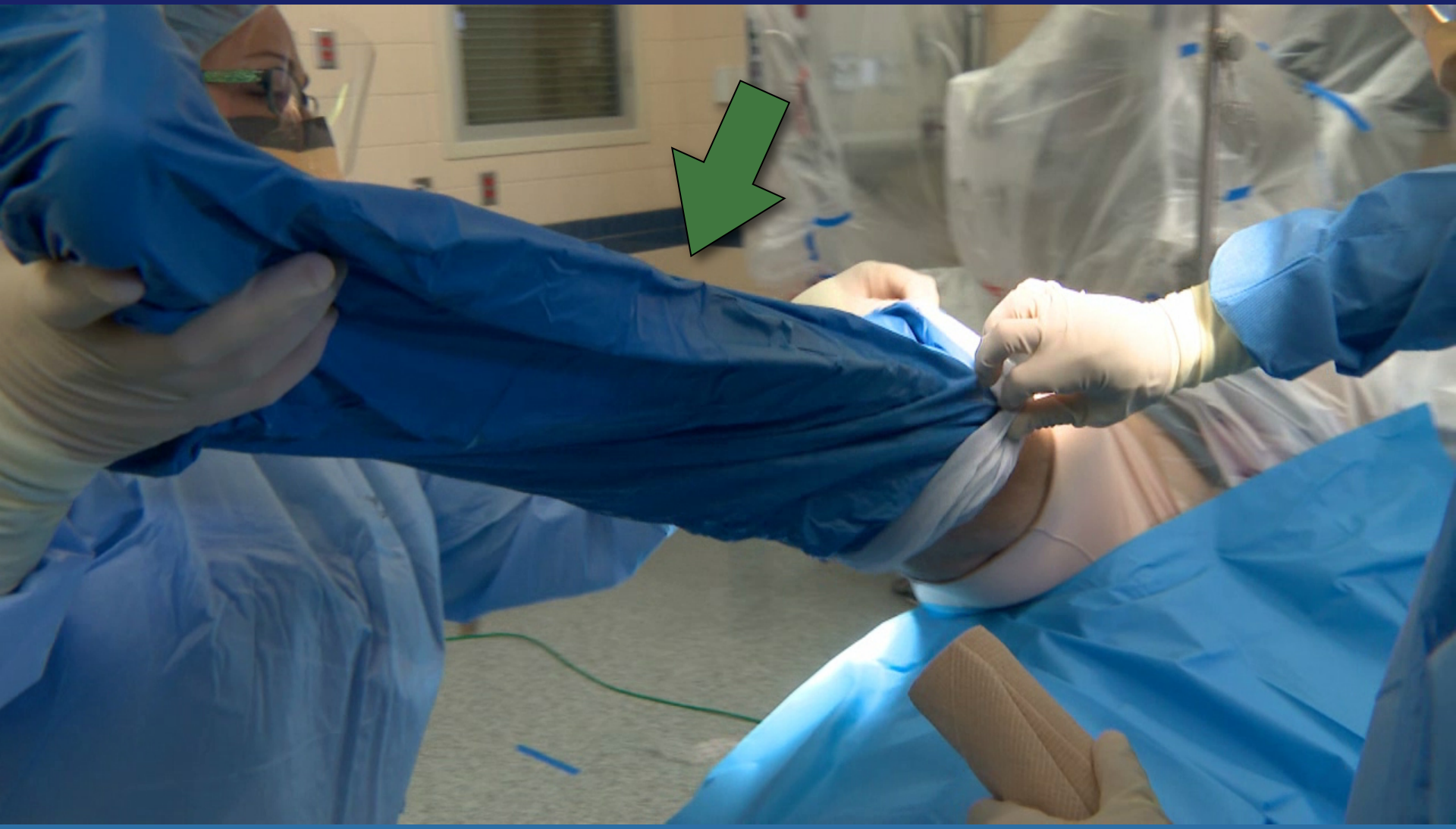


Sterile Drape Over Clear Plastic Drape



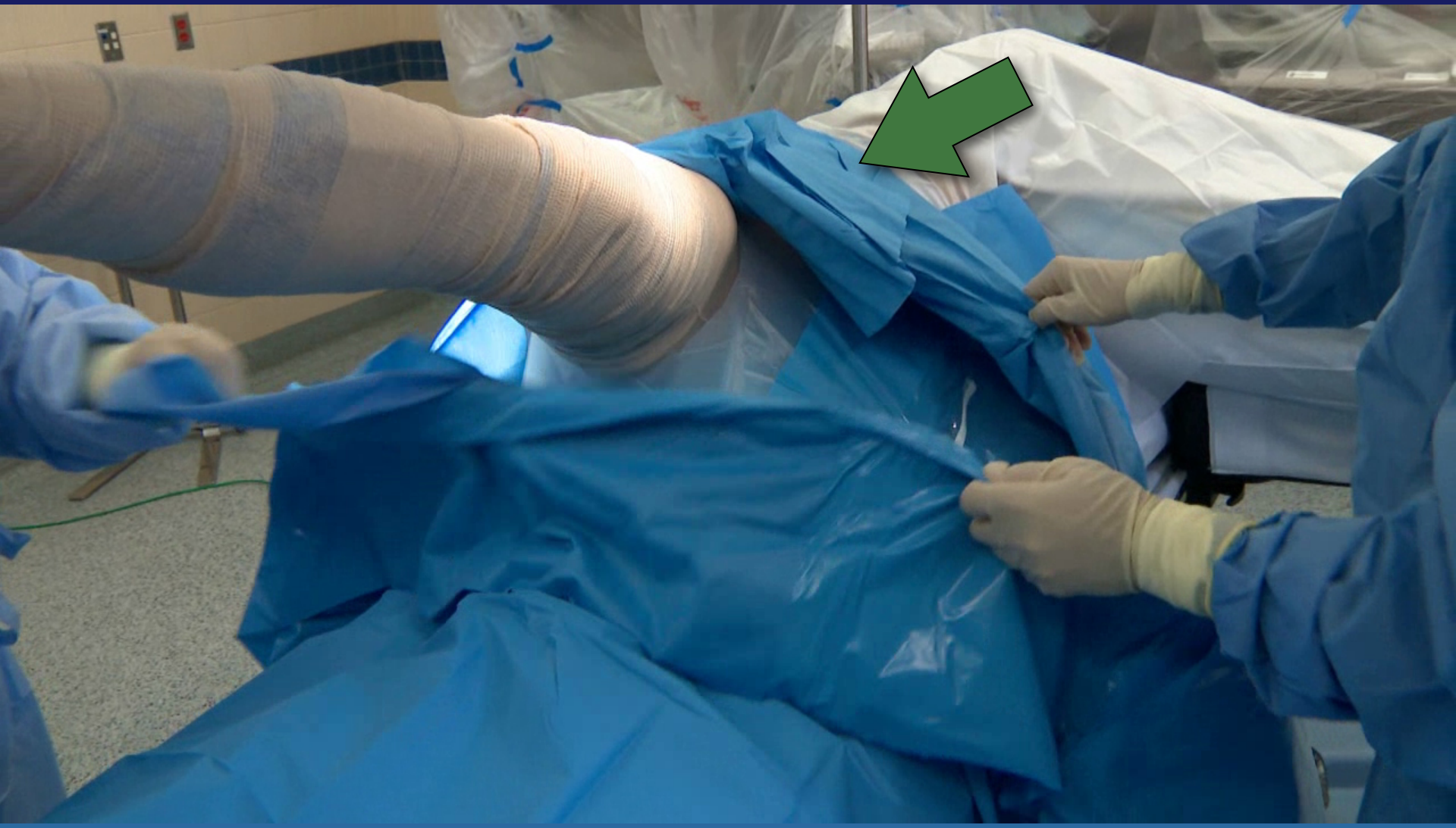
Sterile Split Sheet – Over Sterile Drape and Clear Plastic Drape

Sterile Stocking (Stockinette)



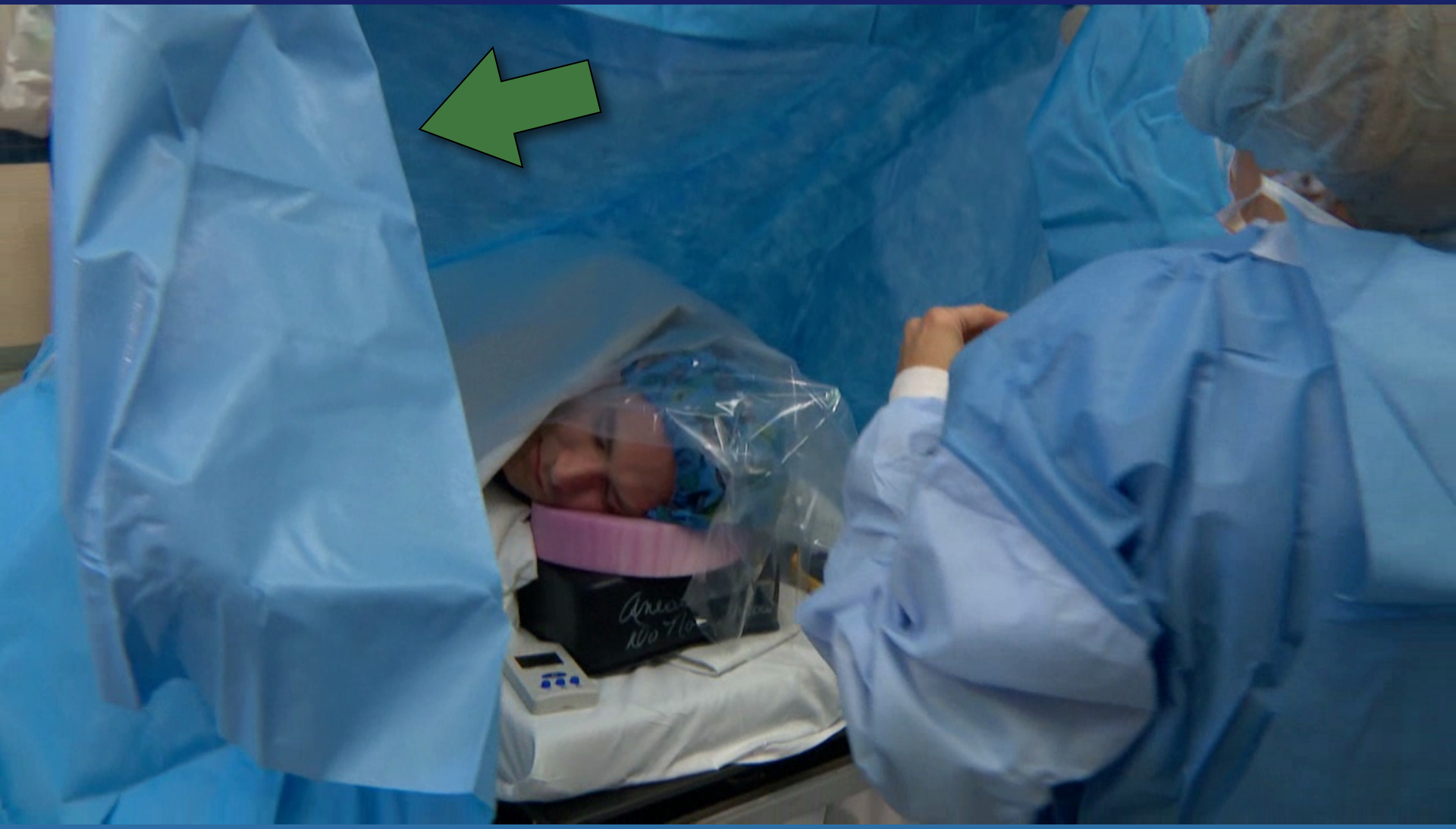
Sterile Drape (Coban) Over Sterile Stocking (Stockinette)

Sterile Hip Drape



Sterile Hip Drape Used as Anesthesia Screen

Sterile Hip Drape Used as Anesthesia Screen

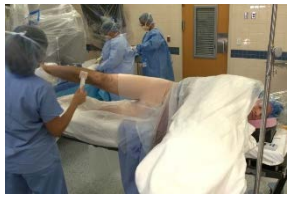


Sterile Drape (Ioban) Placed Directly Over Incision Site

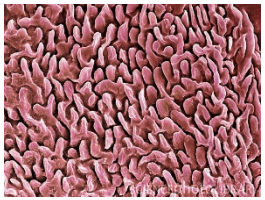
Common Sources of Bacteria in Operating Room

Trash Receptacle

Cabinets along walls

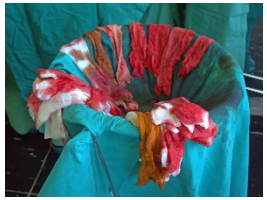


Patient's Skin

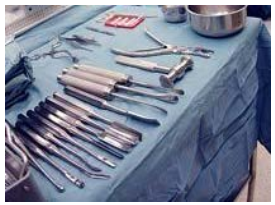


Staff shedding skin cells

Glove perforations

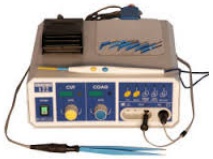


Drop bucket for used sponges



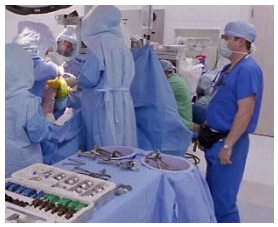
Surgical instruments

Suction drain



Electrocautery machines and other equipment

Anesthesia team and equipment



Circulating nurses

Backs of surgeon & surgical technicians

Lights above operating table

Blood and fluid on sterile drapes

Gown and drape perforations

Cleveland Clinic

Michael Mont, M.D.
Chairman, Department of Or
Adult Hip and Knee Reconst

September 12, 2017

Dear Corey,

I wish to supplement my expert report regarding the 3M litigation because of newly published FDA recommendations for Health Care Providers. In the FDA's August 30, 2017 letter, there is continual recommendation to use forced air warming devices for surgeries as clinically warranted.

The MedSun Medical Product Safety Network's September 2017 FDA release stated the following, which is a direct excerpt:

"Forced Air Thermal Regulating Systems: Healthcare Provider Letter

August 30, 2017

The FDA recently became aware that some health care providers and patients may be avoiding the use of forced air thermal regulating systems during surgical procedures due to concerns of a potential increased risk of surgical site infection (e.g., following joint replacement surgery). After a thorough review of available data, the FDA has been unable to identify a consistently reported association between the use of forced air thermal regulating systems and surgical site infection. FDA continues to recommend the use of thermoregulating devices (including forced air thermal regulating systems) for surgical procedures when clinically warranted."

The FDA's letter is consistent with, further supports and does not change the opinions expressed in my expert report signed June 2, 2017. I intend to rely on this Letter to Health Care Providers in support of my existing opinions and may refer to it at the time of trial.

I certify under penalty of perjury that my statements in this supplemental report executed on September 12, 2017 are true and correct.

Michael Mont, MD
Chairman, Department of Orthopaedics
Cleveland Clinic

The Cleveland Clinic Foundation
Orthopaedic Surgery

9500 Euclid Avenue / A40
Cleveland, Ohio 44195

Tel 216 444-2434
Fax 216 445-6255
Appt 216 444-2606
montm@ccf.org